

23 Feb 2022

Chief of Naval Operations
ATTN: Privacy Act Officer/FOIA Coordinator
Department of the Navy
2000 Navy Pentagon
Washington, DC, 20350-2000

Re: Privacy Act Request for Access to Records ICO LCDR Jason DeJesus

Dear Privacy Act Officer of the Office of the Chief of Naval Operations:

This is a request under the Privacy Act of 1974.

I request a hard or electronic copy of all records pertaining to my religious accommodation file associated with my request for religious accommodation submission maintained at your agency. I am requesting this documentation as it pertains to me and my religious accommodation file and is necessary to make an informed and adequate appeal response. I further request expedited processing because failure to obtain the records on an expedited basis could result in my loss of due process.

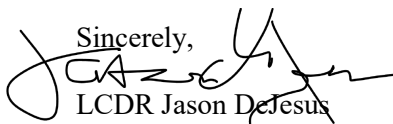
To help you to locate my records, my religious accommodation appeal was received by the DCNO N1's office on 3 November 21 2021. I subsequently received an appeal denial response from the CNO via letter dated 9 February 2022. The requests pertaining to this request would have been accessed, used, and/or considered during that window of time.

To further describe the requested records, I am requesting all documentation used as a reference or for review and consideration in the CNO's determination and response to my religious accommodation appeal. These documents include, but are not limited to, listed references specific to my record, vaccination and COVID-19 statistics, any medical data considered or associated with the determination that unvaccinated individuals provide a higher risk to force than any other group, higher guidance, references, instructions, NAVADMINs, ALNAVs, my religious accommodation package, spreadsheets and/or trackers associated with decision-making if applicable, my personnel record information, etc.

Please consider that this request is also made under the Freedom of Information Act. Please provide any of the above-requested or additional information that would be releasable to me under the FOIA. I understand I am an "other" requestor and am willing to pay any fees associated with this request. Should you require additional information or further clarification to process this request, I may be reached via phone at 760-805-2325 or via email at jason.c.dejesus.mil@us.navy.mil and dejesus.jason@gmail.com.

Thank you for your consideration of this request.

Sincerely,



LCDR Jason DeJesus
2530 Murray Avenue
Norfolk, VA 23518



DEPARTMENT OF THE NAVY

CHIEF OF NAVAL OPERATIONS

2000 NAVY PENTAGON

WASHINGTON DC 20350-2000

1730

N00

9 February 2022

From: Chief of Naval Operations
To: LCDR Jason C. DeJesus, USN
Via: Commander, Carrier Strike Group TWELVE

Subj: APPEAL OF RELIGIOUS ACCOMMODATION FOR IMMUNIZATION
REQUIREMENT ICO LCDR JASON C. DEJESUS, USN

Ref: (a) DCNO (N1) ltr 1730 Ser N1/114601 of 3 Nov 21
(b) DoD Instruction 1300.17 of 1 Sep 2020
(c) SECNAVINST 1730.8B
(d) ASN (M&RA) memo of 6 Jun 13
(e) BUPERSINST 1730.11A
(f) CHBUMED ltr 6320 Ser M44/21UM40506 of 12 Oct 21
(g) NAVADMIN 190/21

1. Your appeal of reference (a) is disapproved. I am disapproving your appeal due to the Navy's compelling governmental interest in preventing infection by and spread of diseases to support mission accomplishment, including military readiness, unit cohesion, good order and discipline, and health and safety, at the individual, unit, and organizational levels. A waiver of immunizations would have a predictable and detrimental effect on the readiness of you and the Sailors who serve alongside you. Granting your request will have a direct and foreseeable negative impact on the compelling governmental interest in military readiness and health of the force. I further find that there are no less restrictive means to achieve the Navy's compelling governmental interest.

2. References (b) through (e) designate me as the final appeal authority for requests for religious accommodation.

3. I considered your original request, your appeal, and the endorsements on your correspondence. Your assignment as a Surface Warfare Officer assigned to a Carrier Strike Group weighed heavily in my consideration of your case. In reviewing your appeal, I evaluated the request under the assumption that your religious beliefs are sincere and would be substantially burdened. As explained in reference (f), while no vaccine is 100 percent effective, vaccines with lower effectiveness still reduce disease incidence in the population, reduce an individual's risk of contracting the disease, and generally reduce the severity of disease for those who do contract the illness. In addition, the current coronavirus disease 2019 (COVID-19) pandemic further highlights the importance of vaccination in both individual and unit force health protection.

Subj: APPEAL OF RELIGIOUS ACCOMMODATION FOR IMMUNIZATION
REQUIREMENT ICO LCDR JASON C. DEJESUS, USN

4. Vaccination of Navy personnel can impact both individual and unit mission accomplishment. It reduces the risk to the individual for disease-related performance impairment, and it reduces the risk to the unit for disease outbreaks of contagious diseases such as COVID-19. While non-pharmaceutical measures such as personal hygiene, mask wearing, and social distancing can also reduce the risk of disease outbreaks, they too are not 100 percent effective and must be implemented in conjunction with immunization to reduce the risk of mission failure. As explained in reference (f), these measures are not as effective as vaccination in maintaining military readiness and the health of the force.

5. My decision is limited to the COVID-19 vaccine only. You also requested an exemption from all other vaccines developed using fetal cell lines derived from aborted fetuses. You are not currently required to receive any of the specific vaccines you listed in your request (MMR, Measles-Rubella, Mumps-Rubella, Rubella, MMR + Chickenpox, Hepatitis A, Hepatitis A & B, and Hepatitis A & Typhoid), and therefore your request is not ripe for review. You may file a religious accommodation request in the future if you are required to take any specific vaccines which substantially burden your sincerely held religious beliefs.

6. You must now become fully vaccinated against COVID-19 in accordance with reference (g). You are free to choose which authorized COVID-19 vaccine to take, but you must receive a vaccine within five calendar days upon receipt of this letter. If you choose a COVID-19 vaccine that requires two doses, you must complete the series as prescribed. You must also receive all other required immunizations as directed by your command and/or primary care manager. These include the influenza (annually), TDaP (every 10 years), and location-specific vaccinations.

7. The Navy welcomes people of all faiths and no faith to join our ranks in patriotic service. Our greater mission sometimes requires reasonable restrictions. You have my sincere best wishes for your continued success in your Navy career.


M. M. GILDAY

Copy to:
ASN (M&RA)
OPNAV (N131)
BUMED



DEPARTMENT OF THE NAVY
CARRIER STRIKE GROUP TWELVE
9756 DECATUR AVENUE SUITE 300
NORFOLK VA 23511-3231

1730
Ser N00/100
20 Sep 21

From: Commander, Carrier Strike Group TWELVE
To: Chief of Naval Operations (N1)

Subj: RECOMMENDATION ICO LCDR JASON DEJESUS FOR RELIGIOUS
ACCOMMODATION

Ref: (a) DoD Instruction 1300.17
(b) SECNAVINST 1730.8
(c) BUPERSINST 1730.11A
(d) BUMEDINST 6230.15B
(e) SECNAV WASHINGTON DC 302126Z Aug 21 (ALNAV 062/21)
(f) CNO WASHINGTON DC 311913Z Aug 21 (NAVADMIN 190/21)

Encl: (1) LCDR DeJesus request dated 16 Sep 21
(2) Chaplain Memorandum and Interview Checklist
(3) Memorandum for the Record ICO LCDR DeJesus
(4) Religious Leader Endorsement from Senior Pastor Clayton Ritter
(5) NAVPERS 1070/63 (REV. 08-2012)
(6) Abortion-Tainted Vaccines for US and Canada and Ethical Alternatives
(7) National Catholic Bioethics Center (NCBC) Statement on COVID-19 Vaccine Mandates
dtd 2 Jul 21

1. Per references (a) through (c), I am forwarding this request recommending disapproval in full or in part during the following environments:

- a. Operational recommendation: Disapproval
- b. Non-operational recommendation: Disapproval
- c. Training environment recommendation: Disapproval

2. The following information was considered or is provided for consideration as applicable:

a. The importance of the military policy, practice or duty from which religious accommodation is sought in terms of mission accomplishment, including:

(1) Military readiness: Due to the highly contagious nature of COVID-19, and the mitigations required for both unvaccinated and vaccinated personnel in the event of COVID infection, readiness would be at increased risk with an unvaccinated member on this Staff. Furthermore, due to the small size of my Staff, the loss of even one Sailor could have significant impact. An outbreak, made more likely by the presence of an unvaccinated Sailor, could put our ability to Command and Control a Carrier Strike Group at risk.

Subj: RECOMMENDATION ICO LCDR JASON DEJESUS FOR RELIGIOUS
ACCOMMODATION

(2) Unit cohesion: Preventative mitigations, including post-travel ROM periods, afford unvaccinated members greater time off due to the limitations of telework. This is already detrimental to unit cohesion and undermines Good Order and Discipline; to continue this practice over a longer timeline would only exacerbate the problem.

(3) Good order and discipline: See comments above.

(4) Health and safety: Unvaccinated Sailors are more likely to communicate the disease within the staff and therefore pose an obvious increased health risk.

b. The religious importance of the practice to the requestor.

c. The cumulative impact of repeated accommodations of religious practices of a similar nature.

d. Alternate means available to accommodate the practice in whole or in part.

3. My point of contact for this matter is (b) (6) Chief of Staff, who can be reached at (b) (6) or (b) (6)

4. This recommendation will be emailed to OPNAV N131 for decision within the timelines in reference (c).

(b) (6)

Copy to:
OPNAV N131
LCDR DeJesus

16 Sep 21

From: LCDR Jason Correa DeJesus, United States Navy
To: Deputy Chief of Naval Operations (Manpower, Personnel, Training and Education)
(CNO N1)
Via: Commander, Carrier Strike Group TWELVE
Subj: REQUEST FOR WAIVER OF POLICY IN SUPPORT OF RELIGIOUS PRACTICE

Ref: (a) DoD Instruction 1300.17 of 1 September 2020
(b) SECNAVINST 1730.8B
(c) BUPERSINST 1730.11A
(d) BUMEDINST 6230.15B
(e) SECNAV WASHINGTON DC 302126Z Aug 21 (ALNAV 062/21)
(f) CNO WASHINGTON DC 311913Z Aug 21 (NAVADMIN 190/21)

Encl: (1) Memorandum for the Record signed LCDR DeJesus dtd 15 Sep 21
(2) Seashore Church Endorsement dtd 19 Jan 21
(3) Abortion-Tainted Vaccines for US and Canada and Ethical Alternatives
(4) NAVPERS 1070/613 (REV. 08-2012)
(5) National Catholic Bioethics Center (NCBC) Statement on COVID-19 Vaccine
Mandates dtd 2 Jul 21
(6) Chaplain Interview Checklist
(7) Chaplain Memorandum For The Record dtd 13 Sep 21

1. Pursuant to references (a) through (c), I hereby request religious accommodation from Navy policy reference (d) and (f) paragraph 2 to be fully vaccinated against COVID-19 through administration of vaccines that have received Food and Drug Administration (FDA) licensure or through the voluntary administration of vaccines under FDA Emergency Use Authorization (EUA) or World Health Organization (WHO) Emergency Use Listing due to my religious belief that injecting vaccines that used aborted fetal cells during the development/production would be a sinful act. Therefore I in good conscience am unable to benefit from using vaccines utilizing aborted fetal cells or introduce into my body anything that I am unwilling to accept.

2. My request is based on my religious belief that:

a. Psalm 127:3 “. . .children are a gift of the Lord, the fruit of the womb is a reward.” Children are pure and should never been an acceptable collateral damage for my benefit. I could not in good conscience be a participant in the sinful acts involving living fetal destruction.

b. 2 Corinthians 1:12 “For our proud confidence is this: the testimony of our conscience, that in holiness and godly sincerity, not in fleshly wisdom but in the grace of God, we have conducted ourselves in the world, and especially toward you.” A clear conscience will be the direct representation of who I am and what I stand for upon the day of judgement. The decisions I made during my time in the Navy were influenced based on a clear conscience that I would absolutely know without a doubt I made the right choices in God’s eyes

Enclosure (1)

Subj: REQUEST FOR WAIVER OF POLICY IN SUPPORT OF RELIGIOUS PRACTICE

c. Matt 9:35 "And Jesus went about all the cities and villages, teaching in their synagogues, and preaching the gospel of the kingdom, and healing every sickness and every disease among the people." I faithfully do not fear death knowing that Jesus will heal all of us when we are in need without the assistance of these vaccines with aborted fetal cells

d. Further explanation is included in enclosure (1) with supporting documentation in enclosures (2) through (7).

3. I certify that I understand that any approved or partially approved waiver may not be appropriate for future duty to which I may be assigned, including operational, non-operational or training command(s), and may be suspended or withdrawn in accordance with reference (c).


J. C. DEJESUS

13 SEP 2021

CHAPLAIN MEMORANDUM FOR THE RECORD

From: (b) (6), CHC, USN
To: Commander, CARRIER STRIKE GROUP TWELVE

Subj: REQUEST FOR A WAIVER OF POLICY TO ACCOMMODATE PRACTICE
BASED ON RELIGIOUS BELIEF ICO LCDR DEJESUS, JASON C

Ref: (a) SECNAVINST 1730.8B CH-1
(b) SECNAVINST 1730.9A
(c) BUPERSINST 1730.11A

1. LCDR DeJesus, Jason has submitted a request for accommodation of a religious practice per reference (a). Per reference (c), I interviewed the requestor on 08 SEP 2021. I explained that this interview would not be a confidential communication as defined by reference (b) and inform me the requestor that referral for confidential chaplain support was available.

2. Nature of the request. LCDR DeJesus, Jason is requesting a religious accommodation from Navy policy for consideration to not receive the COVID-19 vaccine. He has never requested a religious accommodation for this vaccine or any other vaccine, but has not been in a position to need to make that request since the birth of his child. LCDR DeJesus takes the health of his body and his families seriously and the birth of his child has brought focus on only putting the best things in their bodies.

3. Basis. When meeting with LCDR DeJesus, he identified himself as a practicing Christian. Because of his beliefs he communicated that he did not want to receive the vaccine. Because of sincerely held beliefs and foundations of his Christian faith in the Power of God's healing and mercy.

4. Alternate means. No alternate means were identified during this interview, apart from social distance and mask wearing.

5. Sincerity. I believe LCDR DeJesus, Jason's request to be sincere and consistent with his religious faith. He is committed to his faith and being the leader in his home he actively stands for the values his faith demands through actions and not just words.

6. My contact information is (b) (6) or via e-mail at (b) (6)

(b) (6)

Copy to:
LCDR DEJESUS, JASON

Enclosure (2)

Requestor: LCDR DEJESUS, JASON C			Interview Date: 13 SEP 2021
Name:			Chaplain Interviewer: (b) (6)
Phone: 760-805-2325			Phone: (b) (6)
Email: Jason.c.dejesus.mil@us.navy.mil			E-mail: (b) (6) @navy.mil
Command: CSG 12			Chaplain's Command: DESRON 28
Interview Preliminaries			
Yes	No	N/A	
X			Chaplain reviewed policy and doctrine on religious accommodation and the policy for which the requestor is seeking accommodation.
X			Applicant was notified that the interview is not confidential and will be used to advise the command.
X			Chaplain explained to the applicant that confidential support can be received from another chaplain.
	X		Applicant has been granted a waiver for this practice previously.
X			Applicant's Page 2 (NAVPERS 1070/602) reflects the belief cited in the application.
Type of Waiver Requested			
Yes	No	N/A	
			Uniform standards
			Grooming standards
X			Immunization requirements
			DNA sampling
			Other (Please describe):
Interview			
Yes	No	N/A	
X			Requestor's religious beliefs seemed honestly and sincerely held using one or more of the following factors:
X			1. Requestor was credible (consistently keeps tenets, practices, etc.).
X			2. Requestor's demeanor and pattern of conduct are consistent with the request.
X			3. Requestor participates in activities associated with the belief(s).
X			4. Other persons supporting the claim are credible.
X			5. Request is supported by letter(s) of verification or endorsement from an organization espousing the beliefs which are the basis for the claim.
	X		Alternate means of accommodating the practice were explored in the interview.
Process Checklist			
Yes	No	N/A	
X			Chaplain has prepared a memorandum documenting the interview.
X			Chaplain reviewed memorandum with applicant and provided a copy.
X			Chaplain submitted the memorandum and this document to the commanding officer via chain of command.
X			Chaplain referred applicant to command to process request.

16 Sep 21

MEMORANDUM FOR THE RECORD

SUBJECT: Religious Vaccine Accommodation for LCDR Jason Correa DeJesus

1. I, LCDR Jason Correa DeJesus, 1110, permanent resident of the state of CALIFORNIA, currently stationed at Naval Station Norfolk, am exercising my rights under the First Amendment of the U.S. Constitution to declare Religious Accommodation. This declaration is based upon sincerely held religious beliefs that are contrary to the practice of vaccinations using aborted fetal cells without consent.
2. I have lived through a multitude of personal struggles and miracles I truly believe that couldn't have been possible without God by my side. Between the many sea-going and shore commands, I have always been able to seek guidance from the Lord through scriptures and living a righteous life. Our family had to complete another cross-country PCS in late 2019, but this time with a toddler in tow. With no family and friends in the local area, we immediately looked for a local church community to join. My wife is not a Catholic and she would prefer to attend Christian churches so our search began and we eventually landed at Seashore Church. At Seashore, our faith and decisions have been fully supported physically, emotionally, and spiritually (ENCL 2).
3. While being deployed when the global pandemic hit the world, I worried about my family and turned to scripture to pray for the world and my family. Within the year following my return from deployment, the medical community announced the upcoming COVID-19 vaccines that were in development. My wife and I dove in head first and began our journey for information on the vaccines. After 14 years of active duty service, I was unaware of what was used in the development and research that goes into vaccines. The access to information has improved significantly in the last decade and the discovery that aborted fetal cells were used in the vaccine development (ENCL 3) was a shocking revelation. To think that I was to benefit from these aborted babies makes me downhearted and contradicts Psalm 127:3 "...children are a gift of the Lord, the fruit of the womb is a reward." Children are pure and should never be an acceptable collateral damage for my benefit. I could not in good conscience be a participant in the sinful acts involving the living fetal destruction.
4. My conscience is a responsibility that I cannot share and falls solely on me to protect. 2 Corinthians 1:12 "For our proud confidence is this: the testimony of our conscience, that in holiness and godly sincerity, not in fleshly wisdom but in the grace of God, we have conducted ourselves in the world, and especially toward you." A clear conscience will be the direct representation of who I am and what I stand for upon the day of judgement. The decisions I made during my time in the Navy were influenced based on a clear conscience that I would absolutely know without a doubt I made the right choices in God's eyes. Just as in Acts 24:16, "... I also do my best to maintain always a blameless [innocent] conscience both before God and before men." I ultimately must continue my path of righteousness and steer clear of sinful behavior.

Enclosure (3)

SUBJECT: Religious Vaccine Accommodation for LCDR Jason Correa DeJesus

5. Matt 9:35 “And Jesus went about all the cities and villages, teaching in their synagogues, and preaching the gospel of the kingdom, and healing every sickness and every disease among the people.” I faithfully do not fear death knowing that Jesus will heal all of us when we are in need without the assistance of these vaccines with aborted fetal cells. As stated in 1 Corinthians 6:19-20, my body is the Temple of the Holy Spirit and I intend to expose it with substances that will honor God. God will shield me from evil as long as I provide the proper nourishment to my temple. With multiple instances of Lord Jesus Christ healing the sick, I know my strong faith as well as prayers will call to God to protect me and the world.

6. The importance of the military policy, practice or duty from which religious accommodation is sought in terms of mission accomplishment, including:

a. Military readiness: No significant impact. I transferred from a command that strictly adhered to COVID policies and mitigation plans. I spent significant time onboard ships while they were in port and underway without any time away from work due to medical issues. I will continue to follow COVID policies and mitigation measures to include a voluntary ROM period prior to any deployment.

b. Unit cohesion: No impact.

c. Good order and discipline: No impact. In accordance with (IAW) US Code and Military Policy, my accommodation request is aligned with supporting our Department of Defense and Navy’s culture of inclusion, celebrating diversity, and accepting of religious beliefs. I believe the most powerful Navy in the world will fully support our Sailors ability to integrate religious beliefs with military service using the least restrictive means available to support our mission.

d. Health and safety: No impact. I will continue to follow all previously approved COVID mitigations for unvaccinated Sailors which have proven successful to include ROM periods, mask wearing, work space/personal cleanliness, etc.

7. I expect my leaders to uphold the oath to support and defend the United States Constitution and protect my free exercise of religion clause of the First Amendment in declaring religious accommodation from vaccination in accordance with SECNAVINST 1730.8B and BUPERSINST 1730.11A. Please take notice that Title VII of the Civil Rights Act of 1964 as amended November 1, 1980; Part 1605.1 – Guidelines on Discrimination Because Of Religion, employers are prohibited from discriminating in the form of treating an employee with professed religious beliefs differently and cannot impose different work requirements for an employee with professed religious convictions.

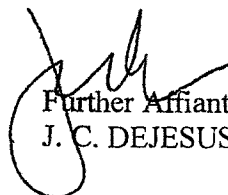
8. The U.S. Supreme Court level in *Frazee V. Illinois Department of Security*, 489 U.S. 829, found that a state may not deny an accommodation simply because a person is not a member of a formal religious organization and I trust that my service to our country which bears the hardship of rooting within a congregation will not be held against me. Furthermore, applicable law has been interpreted to mean that a religious belief is subject to protection even though no religious group espouses such beliefs or the fact that the religious group to which the individual professes to belong may not advocate or require such belief.

SUBJECT: Religious Vaccine Accommodation for LCDR Jason Correa DeJesus

9. This decision is based on my individual spiritual conscience and interpretation to live by God's word and therefore I sincerely hold belief that vaccines are made in violation of God's word, in allowing aborted fetal tissue to be injected into the body. I am submitting this accommodation for all routine and non-routine vaccinations specifically listed below (IAW ENCL 3 and 4):

Disease	Product Name	Manufacturer	Fetal Cell Line
MMR	MMR, Priorix	Merck, GSK	RA273, WI-38, MRC-5
Measles-Rubella	NR Vax, Eolarix	Merck, GSK	RA273, WI-38, MRC-5
Mumps-Rubella	Biavax II	Merck	RA273, WI-38
Rubella	Meruvax II	Merck	RA273, WI-28
MMR+Chickenpox	ProQuad/MMR-V, Priorix Tetra	Merck, GSK	RA273, WI-38, MRC-5
Hepatitis A	Vaqta, Havrix, Avaxim, Epaxal	Merck, GSK, Sanofi, Berna	MRC-5
Hepatitis A&B,	Twinrix, Vivaxim	GSK, Sanofi	MRC-5
Hepatitis A&Typhoid	Twinrix, Vivaxim	GSK, Sanofi	MRC-5
COVID-19		Moderna, Pfizer, Johnson & Johnson AstraZeneca	HEK-293, PER.C6

10. Individuals have always had the ability to think freely and in turn interpret things differently than others. People affiliated with the same groups can also have differences of opinion. IAW (ENCL 5), the NCBC stated "The Church has consistently pointed out the ethical problems with vaccines produced and/or tested using abortion-derived cell lines . . . There is no universal moral obligation to accept or refuse them [vaccines], and it should be a voluntary decision of the individual. Catholic institutions, in particular, should respect the decisions of people to decline use of vaccines dependent on abortion-derived cell lines." Based on my sincere religious convictions assessed by Chaplain Bradley Spear (ENCL 6 and 7) and the mitigations previously listed, I respectfully decline any vaccines that used aborted babies during any point of development or are included in the final solution. There is so much more that I have to offer to the Navy and approving my religious accommodation would allow my continued service to God and our country.


Further Affiant Saith Not
J. C. DEJESUS



January 19, 2021

To Whom It May Concern:

Seashore Church adheres to a biblical model of a life of faith in Jesus Christ for our salvation and our physical, emotional, and spiritual healing. Jesus charged his disciples in Matthew 10:8 to *Heal the sick, raise the dead, cleanse those who have leprosy, drive out demons. Freely you have received; freely give.* The Bible also teaches us that Jesus' sacrifice on the cross provides for our physical healing that is accessed through faith in Him (1 Peter 2:24). While we affirm the benefits of modern medicine, we also affirm that no medical procedure or treatment, including vaccinations, should be forced upon an individual against their will. If a person chooses to live by faith in Jesus in regards to their health, that is their choice to make and should not be forced to vaccinate.

Sincerely,

Clayton Ritter
Senior Pastor
Seashore Church

Enclosure (4)

ADMINISTRATIVE REMARKS

NAVPERS 1070/613 (REV. 08-2012) PREVIOUS EDITIONS ARE OBSOLETE

SUPPORTING DIRECTIVE MILPERSMAN 1070-320

SHIP OR STATION:

COMMANADER CARRIER STRIKE GROUP TWELVE

SUBJECT:

COVID-19 VACCINATION (IMMUNIZATION) EXEMPTION UPON RELIGIOUS REASONS


☐ PERMANENT☐ TEMPORARY

AUTHORITY (IF PERMANENT):

Milpersman 1730-020

Per Milpersman 1730-020 I, LENN JASON DEJESUS request a waiver of the COVID-19 Vaccination. I hereby state that my request is based upon religious objection to immunization. I acknowledge having received the following counseling:

1. Failure to obtain immunization poses additional risk to my health upon exposure to disease.
2. In the event of foreign travel, I may be detained during travel across foreign borders due to international health regulations.
3. If granted, a waiver may be revoked by my commanding officer if I am at imminent risk of disease or due to international health regulations.
4. If my job duties change, I may need to route a new request.
5. If I am at my permanent change of station while my waiver is in effect, I may need to route a new request if my job duties change, my geographic region exposes me to the aforementioned disease, or other factors exist that could put me at imminent risk of disease.


Service Member's Signature

Witnessed:

(b) (6)

CAPT USN

ENTERED AND VERIFIED IN ELECTRONIC SERVICE RECORD:

VERIFYING OFFICIAL RANK OR GRADE/TITLE:

DATE:

SIGNATURE OF VERIFYING OFFICIAL:

NAME (LAST, FIRST, MIDDLE):

DEJESUS, JASON, CORREA

SOCIAL SECURITY NUMBER:

572-93-0001

BRANCH AND CLASS:

USN AD

FOR OFFICIAL USE ONLY
PRIVACY SENSITIVE

Enclosure (5)



Children of God for Life is the pro-life worldwide leader in the campaign for ethical biomedical research and commerce that preserves the dignity of human life.

Abortion-Tainted Vaccines for US and Canada and Ethical Alternatives

DISEASE	PRODUCT NAME	MANUFACTURER	FETAL CELL LINE	ETHICAL VERSION	MANUFACTURER	CELL
ACUTE RESPIRATORY	Adenovirus 4, 7 Oral	Barr Labs	WI-38, HEK-293	None	NA	NA
CHICKENPOX	All Varivax, Varilrix	Merck, GSK	WI-38, MRC-5	None	NA	NA
COVID-19	See here.	Moderna, Pfizer, J&J, AstraZeneca	HEK-293, PER.C6	None	NA	NA
EBOLA	Advac, VSV-EBOV	J&J/Cruc, BioProt	HEK-293, PER.C6	Ervebo (rVSV-ZEBOV) 2-2020	Merck	Vero
HEPATITIS A	Vaqta, Havrix,	Merck, GSK, Sanofi,	PER.C6	Aimmugen (None in US or Canada)	Kaketsuken (Japan Only)	Vero
HEPATITIS A&B, HEPATITIS A&TYPHOID INFECTION	Avaxim, Epaxal	Berna	MRC-5	Engerix Hep-B Only, Recombivax	GSK, Merck, Sanofi	Yeast
PREVENTION	Twinrix, Vivaxim	GSK, Sanofi	MRC-5	Hep-B, TyphimVi		
MEASLES, MUMPS, RUBELLA	G-CSF	Octapharma	HEK-293	Neupogen, Zarxio	Amgen, Sandoz	E-coli
MEASLES-RUBELLA	MMR, Priorix	Merck, GSK	RA273, WI-38, MRC-5	MR+M (Japan Only)	Mitsubishi, Kitasato	Egg, Rabbit
MUMPS-RUBELLA	NR Vax, Eolarix	Merck, GSK	RA273, WI-38, MRC-5	Attenuvax (Measles Only)* AIK-C+R, Tanabe (Japan)	Merck, Kitasato, Mitsubishi	Egg, Rabbit
RUBELLA	Meruvax II	Merck	RA273, WI-38	Mumpsavax (Mumps Only)*	Merck	Egg
MMR+CHICKENPOX	ProQuad/MMR-V, Priorix Tetra	Merck, GSK	RA273, WI-38, MRC-5	Matsuura, Takahashi (Japan)	Mitsubishi, Kitasato	Egg, Rabbit
RABIES	Imovax	Sanofi	MRC-5	None	NA	NA
SHINGLES	Zostavax	Merck	WI-38, MRC-5	RabAvert	GSK	Egg
SMALLPOX	Acambis 1000	Acambis	MRC-5	Shingrix	GSK	Hamster

Note: ImmuneGlobulin shots will provide temporary immunity (4-6 months) for Hepatitis-A and Rubella (3-4 months).
***Ethically produced separate doses of measles and mumps vaccines are unavailable. Merck stopped providing them.**
 If the vaccine you are questioning is not listed, then to our knowledge it is not abortion-tainted.

Enclosure (6)



THE NATIONAL CATHOLIC BIOETHICS CENTER

6399 Drexel Road, Philadelphia, PA 19151 • Tel 215-877-2660 • Fax 215-877-2688 • www.ncbcenter.org

NCBC Statement on COVID-19 Vaccine Mandates

The National Catholic Bioethics Center (NCBC) does not endorse mandated COVID-19 immunization with any of the three vaccines that have received Emergency Use Authorization as of July 1, 2021, from the US Food & Drug Administration (FDA).

The most authoritative guidance from the Catholic Church issued on this topic comes from the Congregation for the Doctrine of the Faith (CDF) and emphasizes that individuals must discern whether to be vaccinated or not in conscience and without coercion:

“Practical reason makes evident that vaccination is not, as a rule, a moral obligation and that, therefore, it must be voluntary. In any case, from the ethical point of view, *the morality of vaccination depends not only on the duty to protect one's own health, but also on the duty to pursue the common good*. In the absence of other means to stop or even prevent the epidemic, the common good may recommend vaccination, especially to protect the weakest and most exposed. Those who, however, for reasons of conscience, refuse vaccines produced with cell lines from aborted fetuses, must do their utmost to avoid, by other prophylactic means and appropriate behavior, becoming vehicles for the transmission of the infectious agent.”¹

Several key points should be kept in mind by any institution that might consider incentivizing or requiring the use of COVID-19 vaccines currently available in the USA.

1. The Church has consistently pointed out the ethical problems with vaccines produced and/or tested using abortion-derived cell lines. The Church has judged it permissible for people to either accept (under protest) or reject the use of such vaccines.² In other words, there is no universal moral obligation to accept or refuse them, and it should be a voluntary decision of the individual. Catholic institutions, in particular, should respect the decisions of people to decline use of vaccines dependent on abortion-derived cell lines. This is especially relevant when there are other means of mitigating risk.
2. The best ethical decision-making occurs when individuals have sufficient information for discernment and are able to reflect without undue external pressures placed on them. Mandates, by their very nature, exert pressure that can be severe if employment or the ability to further one's education are threatened.
3. The novelty of the SARS-CoV-2 and of the technologies for eliciting an immune response to prevent or mitigate COVID-19 leave several medical questions unanswered. Only time and

¹ https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20201221_nota-vaccini-anticovid_en.html

² <https://www.ncbcenter.org/ncbc-news/vaccinestatementupdated>

careful study of the virus and benefits and adverse effects of the vaccines will provide the answers many persons need to give free and informed consent.

4. If any institution mandates COVID-19 vaccination, the NCBC strongly urges robust, transparent, and readily accessible exemptions for medical, religious, and conscience reasons. Safeguarding the appropriate judgments of conscience³ of all individuals affiliated with the institution helps establish trust and avoid undue pressure during the important and personal process of deciding about appropriate medical care and serving the common good.
5. Recognizing the importance of public health, institutions that grant an exemption may require that recipients restrict their interpersonal interactions, but these restrictions should be the least burdensome possible.

³ Catechism of the Catholic Church sections 1776-1802, and especially 1790.



DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON DC 20350-2000

1730
Ser N1/114601
3 Nov 21

From: Deputy Chief of Naval Operations (Manpower, Personnel, Training and Education) (N1)
To: LCDR Jason C. DeJesus, USN
Via: Commander, Carrier Strike Group TWELVE

Subj: REQUEST FOR RELIGIOUS ACCOMMODATION THROUGH WAIVER OF
IMMUNIZATION REQUIREMENTS

Ref: (a) 42 U.S.C. §2000bb-1
(b) DoD Instruction 1300.17 of 1 September 2020
(c) SECNAVINST 1730.8B
(d) ASN (M&RA) memo of 6 Jun 13
(e) MILPERSMAN 1730-020
(f) United States Attorney General memo of 6 Oct 17
(g) Your ltr of 16 Sep 21 w/ends
(h) BUMED ltr 6320 Ser M44/21UM40506 of 12 Oct 21

1. Pursuant to references (a) through (h), your request for religious accommodation through waiver of immunization requirements is disapproved. You must receive all required vaccines. However, you are free to request from your healthcare provider alternative vaccines that are available and meet the Navy's immunization requirements, as determined by a credentialed military healthcare provider. You are free to choose which COVID-19 vaccine to take. If you choose a COVID-19 vaccine that requires two doses, you must receive your first dose within five calendar (5) days upon receipt of this letter and complete the series as prescribed. If you choose a one-dose vaccine you must meet the established vaccination timeline or receive the vaccine within five calendar (5) days upon receipt of this letter, whichever is later.

2. In line with references (b) through (d), I am designated as the approval authority for requests for religious accommodation.

3. Reference (a), the Religious Freedom Restoration Act (RFRA), states that the Government may substantially burden an individual's exercise of religion only if it demonstrates that application of the burden to the person is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that interest. Reference (b) incorporates the RFRA and notes that the Government has a compelling interest in mission accomplishment, to include military readiness, unit cohesion, good order and discipline, health and safety, on both individual and unit levels. Additionally, unless it will have an adverse impact on mission accomplishment, including military readiness, unit cohesion and good order and discipline, the Navy will accommodate individual expressions of sincerely held beliefs of Sailors. Reference (f)

Subj: REQUEST FOR RELIGIOUS ACCOMMODATION THROUGH WAIVER OF
IMMUNIZATION REQUIREMENTS

emphasizes that only those interests of the highest order can overbalance legitimate claims to the free exercise of religion.

4. All requests for accommodation of religious practices are assessed on a case-by-case basis. In line with references (b) and (c), determination of a request for religious accommodation requires consideration of the following factors:

- a. Impact on military readiness, unit cohesion, good order and discipline, health and safety
- b. Religious importance of the request
- c. Cumulative impact of repeatedly granting similar requests
- d. Whether there are alternatives available to meet the requested accommodation and
- e. How other such requests have been treated

5. In making this decision, I reviewed reference (g), including the endorsements from your chain of command, the local chaplain and the advice of Chief, Bureau of Medicine and Surgery in reference (h).

a. A waiver of immunizations would have a predictable and detrimental effect on your readiness and the readiness of the Sailors who serve alongside you in both operational and non-operational (including training) environments. Primary prevention of disease through immunizations has been a key enabler for maintaining force health and avoiding disease-related non-battle injury. Granting your request will have a direct and foreseeable negative impact on the compelling Government interests of military readiness and health of the force.

b. While serving in the U.S. Navy, you will inevitably be expected to live and work in close proximity with your shipmates. I find that disapproval of your request for a waiver of immunization requirements is the least restrictive means available to preserve the Department of Defense's compelling interest in military readiness, mission accomplishment and the health and safety of military Service Members.

6. The Navy is a specialized community governed by a discipline separate from that of the rest of society. While every Sailor is welcome to express a religion of choice or none at all, our greater mission sometimes requires reasonable restrictions. You have my sincere best wishes for your continued success in your Navy career.

JOHN B. NOWELL, JR

Copy to:
OPNAV (N131, N0975)
BUMED



DEPARTMENT OF THE NAVY
CARRIER STRIKE GROUP TWELVE
9756 DECATUR AVENUE SUITE 300
NORFOLK VA 23511-3231

1412
Ser N00/128
19 Nov 21

FIRST ENDORSEMENT on LCDR Jason C. Dejesus, USN, 1110 ltr 1412 of 19 Nov 21

From: Commander, Carrier Strike Group TWELVE
To: Chief of Naval Operations (CNO)
Via: Deputy Chief of Naval Operations (Manpower, Personnel, Training and Education) (N1)

Subj: APPEAL OF DENIAL OF REQUEST FOR WAIVER FROM THE COVID-19
VACCINATION IN SUPPORT OF RELIGIOUS PRACTICE ICO LCDR JASON C.
DEJESUS LTR DATED 16 SEP 21

Encl: (1) Appeal of denial of request for waiver from the COVID-19 vaccination in support of
religious practice ICO LCDR Jason C. Dejsus LTR dated 16 Sep 21
(2) Request for religious accommodation through waiver of immunization requirements

1. Forwarded. Recommend disapproval.

(b) (6)

Copy to:
LCDR Dejesus

19 Nov 21

From: LCDR Jason C. DeJesus, USN
To: Chief of Naval Operations (CNO)
Via: Commander, Carrier Strike Group TWELVE
Deputy Chief of Naval Operations (Manpower, Personnel, Training and Education) (N1)

Subj: APPEAL OF DENIAL OF REQUEST FOR WAIVER FROM THE COVID-19
VACCINATION IN SUPPORT OF RELIGIOUS PRACTICE ICO LCDR JASON C.
DEJESUS LTR DATED 16 SEP 21

Ref: (a) DoD Instruction 1300.17 of September 1, 2020
(b) SECNAVINST 1730.8 CH-1 of 28 Mar 2021
(c) BUPERSINST 1730.11A of 16 Mar 2021
(d) NAVADMIN 190/21
(e) NAVADMIN 235/21
(f) NAVADMIN 249/21

Encl: (1) CNO N1 ltr of 3 Nov 21 Denial of Religious Accommodations
(2) Religious accommodation request ICO LCDR Jason C. DeJesus, dtd 16 Sep 21

1. Pursuant to references (a) through (c), I hereby appeal VADM Nowell's decision to deny my religious-accommodation request in enclosure (1) for waiver of required immunization due to the use of aborted fetal cells during research, development, and production of vaccines as requested in enclosure (2).

2. As a point of clarification from the SECDEF's Memo dtd 24 August 2021, his direction was for "Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance." The U.S. National Library of Medicine announced on 13 September 2021 that "Pfizer does not plan to produce any product with [Comirnaty] NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution"

3. References (a) through (d) stated that each Sailor's religious accommodation would be reviewed on a case by case basis to determine if accommodations could be met without detriment to unit readiness. It is quite apparent that my denial letter was not specific to me and how my vaccination status affects mission accomplishment at my duty station.

4. According to 42 USC Chapter 21B 2000bb, Congress finds that the framers of the Constitution, recognizing free exercise of religion as an unalienable right, secured its protection in the First Amendment to the Constitution. Additionally, the compelling interest test as set forth in prior Federal court rulings is a workable test for striking sensible balances between religious liberty and competing prior governmental interests.

5. The denial letter states in paragraph 3 that per 42 U.S.C. 2000bb-1, the Religious Freedom Restoration Act (RFRA), states that the government may substantially burden an individual's exercise of religion only if it demonstrates that application of the burden to the person is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that interest. As listed the Government has a compelling interest in mission accomplishment, to include military readiness, unit cohesion, good order and discipline, health and safety, on both individual and unit levels. CNO N1 did not engage in any particular assessment of how accommodating my religious practice would adversely impact any of these compelling interests. The particularized assessment CNO N1 should have conducted is as follows, and arguably would have resulted in an approval of my accommodation request.

a. Military Readiness

- (1) I was embarked on the HARRY S TRUMAN Strike Group from January-June 2020 where we deployed in the 5th, 6th, 4th, and 2nd Fleet AORs. While on the HARRY S TRUMAN, we enjoyed 2 port visits to Duqm, Oman.
- (2) Upon returning to home port, I was allowed to work every day in our office due to social distancing and the needs of the command. From July 2020-May 2021, I was personally involved in ensuring 6 ships left the maintenance phases on time, executed numerous readiness evaluations, and prepared 3 ships for INSURVs.
- (3) I also embarked on our Destroyer Squadron Ships for the majority of the KTR sea trials, readiness evaluations, and INSURVs. My last underway was during a month-long exercise SWATT/GRUSAIL.
- (4) I spent approximately 17 months conducting business as usual with the normal mitigations of mask wearing, social distancing, and regular testing when required.
- (5) These mission-necessary evolutions were successfully accomplished *with my full involvement as a then-unvaccinated service member*. There is **no evidence** in CNO N1's analysis suggesting that similarly important evolutions would be adversely affected should I remain in an unvaccinated status.
- (6) Moreover, as per NAVADMIN 249/21 *CCDA Data Reporting Requirements*, our Active Duty Navy service members are over 99 percent vaccinated which would establish population immunity by some of the best expert estimates. Also in accordance with NAVADMIN 235/21 *2021-2022 Navy Influenza vaccination and reporting policy*, a 90 percent is required for reporting in MRRS for Active and Reserve Component. It is safe to reason that we don't need 100 percent vaccinated to maintain military readiness and health of the force. For example:

Understanding herd immunity: Dr. Gregory Poland, a Mayo Clinic infectious diseases expert and director of the Vaccine Research Group stated, "We know with influenza we need somewhere around 60% of the population to be immune to have herd protection, with measles it's about 95%. The novel coronavirus is probably going to fall into the neighborhood of 70% or

so". *Mayo Clinic News Network* (May 4th, 2020)
<https://newsnetwork.mayoclinic.org/discussion/understanding-herd-immunity/>

b. Good Order and Discipline

- (1) Requesting for a religious accommodation is in line with SECNAVINST 1730.8B, BUMEDINST 6230.15B, BUPERSINST 1730.11A, DODI 1300.17, MILPERSMAN 1730-020, and several other guidance documents. The submission is IAW supported documentation and within policies and regulations where good order and discipline becomes a non-issue. CNO N1 presents no evidence that a properly requested, approved, and documented accommodation in my case would have any tangible effect on order and discipline. Such accommodation would be consistent with current regulations; it is counterintuitive to argue that acting in conformity with regulations undermines good military order.
- (2) VADM Nowell stated in his *U.S. Navy Inclusion and Diversity 2020*, "The importance of both inclusion and diversity cannot be overstated. It is imperative we draw on the diverse resources, skills, capabilities, and talents of our people, and that we not think, and act, and look the same. Equally, we must be inclusive - creating a culture where everyone feels they can provide their opinions and is valued for who they are." My request to be exempt from receiving the mandatory COVID 19 due to my sincerely held religious beliefs is a manifestation of the diversity that CNO N1 states should be valued and is consistent with order and discipline.

c. Health and Safety

- (1) The COVID-19 Vaccine requirement is not narrowly tailored towards achieving the mission accomplishment governmental interest in stemming the spread of COVID-19. The requirement must be "narrowly tailored" or in other words, the "least restrictive means necessary" to stem the spread of COVID-19.
- (2) Another noteworthy example of an individual who recently tested positive for COVID-19, was White House Press Secretary Jen Psaki who was vaccinated by the same vaccines that I am requesting an accommodation for. Mitigation protocols like masking, remote teleworking, physical distancing, and regular testing would still be required regardless of vaccination status because vaccinated personnel can also carry, transmit, and become sick with COVID-19. Centers for Disease Control and Prevention, "Science Brief: COVID-19 Vaccines and Vaccination, (last updated September 15, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>.
- (3) United States Court of Appeals for the Fifth Circuit (12 Nov 2021), "the Mandate fails to consider what is perhaps the most salient fact of all: the ongoing threat of COVID-19 is more dangerous to *some* employees than to *other* employees. All else equal, a 28 year old trucker spending the bulk of his workday in the solitude of his cab is simply less vulnerable to COVID-19 than a 62 year old prison janitor.

Likewise, a naturally immune unvaccinated worker is presumably at less risk than an unvaccinated worker who has never had the virus. . . the Mandate fails almost completely to address, or even respond to, much of this reality and common sense.”

- (4) The least restrictive means of accomplishing the government’s compelling interest was operating for over a year during the COVID-19 pandemic with a ready and healthy force that was not fully vaccinated, and either of the reasons for exemption from vaccination - religious or medical -will not impact a service member’s deployability or the lesser restrictive methods of mitigating the spread of COVID-19 that the Navy can adopt. If those with a medical accommodation could be deployed, so too could those with a religious accommodation.

6. CNO N1 has made clear that his policy is to separate all unvaccinated service members who do not have an approved exemption. It is arguably impossible for him to demonstrate that my remaining in the service while unvaccinated has a more detrimental effect on readiness and similar compelling interests than my being removed from service. If the Navy is genuinely concerned about my infecting other Sailors, I could be left to perform necessary duties in a non-seagoing, non-close-quarters environment. In such a case I would be contributing *more* to the mission than I would be if separated. By announcing a policy of separation for all non-exempt, unvaccinated service members, the Navy has effectively conceded that it can continue to make the contribution to national security that Title 10 requires *without the contributions of the unvaccinated*. To the extent that the Navy’s compelling government interest can be achieved *without me in the service*, it can certainly be achieved with my performing in whatever reduced operating posture the Navy would need to impose should it desire my physical separation from my shipmates.

7. CNO N1 has not provided evidence to prove that my being vaccinated is the minimally offensive way (with respect to my free exercise of religion) to achieve the government’s compelling interest. Consequently, his denial of my accommodation was improper, and I recommend that this appeal be approved.

8. For any questions in this matter, I may be reached via phone at 760-805-2325 or via email at jason.c.dejesus.mil@us.navy.mil.


J. C. DEJESUS



DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON DC 20350-2000

1730
Ser N1/114601
3 Nov 21

From: Deputy Chief of Naval Operations (Manpower, Personnel, Training and Education) (N1)
To: LCDR Jason C. DeJesus, USN
Via: Commander, Carrier Strike Group TWELVE

Subj: REQUEST FOR RELIGIOUS ACCOMMODATION THROUGH WAIVER OF
IMMUNIZATION REQUIREMENTS

Ref: (a) 42 U.S.C. §2000bb-1
(b) DoD Instruction 1300.17 of 1 September 2020
(c) SECNAVINST 1730.8B
(d) ASN (M&RA) memo of 6 Jun 13
(e) MILPERSMAN 1730-020
(f) United States Attorney General memo of 6 Oct 17
(g) Your ltr of 16 Sep 21 w/ends
(h) BUMED ltr 6320 Ser M44/21UM40506 of 12 Oct 21

1. Pursuant to references (a) through (h), your request for religious accommodation through waiver of immunization requirements is disapproved. You must receive all required vaccines. However, you are free to request from your healthcare provider alternative vaccines that are available and meet the Navy's immunization requirements, as determined by a credentialed military healthcare provider. You are free to choose which COVID-19 vaccine to take. If you choose a COVID-19 vaccine that requires two doses, you must receive your first dose within five calendar (5) days upon receipt of this letter and complete the series as prescribed. If you choose a one-dose vaccine you must meet the established vaccination timeline or receive the vaccine within five calendar (5) days upon receipt of this letter, whichever is later.

2. In line with references (b) through (d), I am designated as the approval authority for requests for religious accommodation.

3. Reference (a), the Religious Freedom Restoration Act (RFRA), states that the Government may substantially burden an individual's exercise of religion only if it demonstrates that application of the burden to the person is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that interest. Reference (b) incorporates the RFRA and notes that the Government has a compelling interest in mission accomplishment, to include military readiness, unit cohesion, good order and discipline, health and safety, on both individual and unit levels. Additionally, unless it will have an adverse impact on mission accomplishment, including military readiness, unit cohesion and good order and discipline, the Navy will accommodate individual expressions of sincerely held beliefs of Sailors. Reference (f)

Enclosure (1)

Subj: REQUEST FOR RELIGIOUS ACCOMMODATION THROUGH WAIVER OF
IMMUNIZATION REQUIREMENTS

emphasizes that only those interests of the highest order can overbalance legitimate claims to the free exercise of religion.

4. All requests for accommodation of religious practices are assessed on a case-by-case basis. In line with references (b) and (c), determination of a request for religious accommodation requires consideration of the following factors:

- a. Impact on military readiness, unit cohesion, good order and discipline, health and safety
- b. Religious importance of the request
- c. Cumulative impact of repeatedly granting similar requests
- d. Whether there are alternatives available to meet the requested accommodation and
- e. How other such requests have been treated

5. In making this decision, I reviewed reference (g), including the endorsements from your chain of command, the local chaplain and the advice of Chief, Bureau of Medicine and Surgery in reference (h).

a. A waiver of immunizations would have a predictable and detrimental effect on your readiness and the readiness of the Sailors who serve alongside you in both operational and non-operational (including training) environments. Primary prevention of disease through immunizations has been a key enabler for maintaining force health and avoiding disease-related non-battle injury. Granting your request will have a direct and foreseeable negative impact on the compelling Government interests of military readiness and health of the force.

b. While serving in the U.S. Navy, you will inevitably be expected to live and work in close proximity with your shipmates. I find that disapproval of your request for a waiver of immunization requirements is the least restrictive means available to preserve the Department of Defense's compelling interest in military readiness, mission accomplishment and the health and safety of military Service Members.

6. The Navy is a specialized community governed by a discipline separate from that of the rest of society. While every Sailor is welcome to express a religion of choice or none at all, our greater mission sometimes requires reasonable restrictions. You have my sincere best wishes for your continued success in your Navy career.

(b) (6)
JOHN B. NOWELL, JR

Copy to:
OPNAV (N131, N0975)
BUMED



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH VA 22042

IN REPLY REFER TO
6320
Ser M44/21UM40506
12 Oct 21

From: Chief, Bureau of Medicine and Surgery
To: Deputy Chief of Naval Operations (Manpower, Personnel, Training, and Education) (N1)

Subj: REQUEST FOR RELIGIOUS ACCOMMODATION THROUGH WAIVER OF
IMMUNIZATION REQUIREMENTS ICO LCDR JASON C. DEJESUS, USN

Ref: (a) LCDR DeJesus' Waiver Request of 16 Sep 21
(b) BUMED Memo, Diseases Targeted with Mandatory Vaccinations for U.S.
Navy Active Duty and Reserve Personnel of 22 Sep 21
(c) BUMED INST 6230.15B, Immunizations and Chemoprophylaxis for the Prevention
of Infectious Diseases, 7 Oct 2013
(d) SECNAVINST 1730.8B CH-1

1. Subject matter experts at the Bureau of Medicine and Surgery have reviewed reference (a). Per reference (a), LCDR DeJesus objects to receiving all immunizations developed or tested using fetal cells based on his religious beliefs.

2. Fetal embryo fibroblast cells are used to grow viruses for multiple vaccines, including adenovirus, varicella (chickenpox), rubella (the "R" in the MMR vaccine), hepatitis A, one preparation of rabies vaccine, two combination vaccines containing the polio vaccine virus, and two formulations of zoster (shingles) vaccine. The FDA-approved Coronavirus Disease 2019 (COVID-19) vaccine did not require the use of any fetal cell cultures in order to manufacture the vaccine, however, early in the development of mRNA vaccine technology, fetal cells were used for "proof of concept" or to characterize the SARS-CoV-2 spike protein. All other vaccines, including tetanus, diphtheria, pertussis, influenza, etc., are not derived from fetal cells. No alternative formulations grown without fetal cells are currently available for COVID-19, adenovirus, varicella, rubella, and hepatitis A vaccines.

3. All vaccines required for maintenance of individual medical readiness and vaccines required for specific overseas deployments meet the safety requirements of the U.S. Food and Drug Administration (FDA), and have demonstrated effectiveness in disease prevention.

4. Per reference (c), Active Duty and Reserve Component personnel will receive or be up-to-date on adult routine vaccinations. Details of required vaccinations are outlined in this instruction and are available at www.health.mil/vaccines.

5. A waiver of immunization requirements would have detrimental effects on the readiness of both LCDR DeJesus and Service members who serve alongside LCDR DeJesus. Primary prevention of disease through immunizations is a key enabler for maintaining force health protection and avoiding disease-related non-battle injury, and has been the cornerstone of these efforts for decades. Recent outbreaks of contagious viral diseases aboard Navy ships highlight

Subj: RELIGIOUS ACCOMMODATION REQUEST THROUGH WAIVER OF
IMMUNIZATION REQUIREMENTS ICO LCDR JASON C. DEJESUS, USN

the operational impact of low levels of immunity. Diseases such as COVID-19 are highly contagious and can rapidly degrade individual and unit readiness. In the current COVID-19 pandemic, the outbreak aboard the *USS THEODORE ROOSEVELT* in March 2020, resulted in 71 days of unavailability for a forward deployed aircraft carrier. There was an infection rate of more than 26% of the crew as confirmed by laboratory testing within 5 weeks of the initial positive case (including four hospitalizations and one death, according to data published in Journal of The American Medical Association 11 November 2020). This outbreak resulted in crew-wide quarantine, isolation, and repeated testing, and highlights the importance of vaccination to both individual and unit force health protection. Additional information on the potential impacts of vaccine-preventable diseases is provided in reference (b).

6. The scientific and medical communities believe that SARS-CoV-2 will likely remain in global circulation as an endemic virus and a threat to the Force. The emergence of the SARS-CoV-2 Delta variant shows that while some vaccinated personnel may transmit the virus, they are largely protected against severe illness and death. Unvaccinated individuals remain at risk for developing COVID-19 and propagating new variants that may adversely impact the readiness of the Force.

7. Vaccination remains the most effective means to prevent COVID-19 (as well as influenza, pertussis, diphtheria, tetanus, and other diseases). Optimally, vaccination should be coupled with other countermeasures to minimize risk of infections to the Sailor's health, co-workers' health, and to Navy's mission. In large phase III trials, the FDA-approved COVID-19 vaccine demonstrated over 94% efficacy in preventing symptomatic COVID-19. For the same vaccine, against the Delta variant in a real world setting, studies show 88% effectiveness against symptomatic disease, to include hospitalization and death. Additional information on the efficacy of other vaccines is provided in reference (b).

8. Per reference (d), the religious objection of the Service member must be balanced against the medical risk to the Service member and their military unit. The Department of Defense has a compelling interest in mission accomplishment and safeguarding the health of military Service members. In this case, the medical risks of not receiving required vaccines outweigh the religious objection that LCDR DeJesus has stated in reference (a).

9. A waiver of required immunizations is not recommended due to the aforementioned reasons.

10. My point of contact is (b) (6) MC, USN, Preventive Medicine, who can be reached at (b) (6)

Deputy Chief
Business Operations



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH VA 22042

IN REPLY REFER TO

6320

Ser M44/21UM401

22 Sep 21

From: Chief, Bureau of Medicine and Surgery

To: Deputy Chief of Naval Operations, Manpower, Personnel, Training, and Education (N1)

Subj: DISEASES TARGETED WITH MANDATORY VACCINATIONS FOR UNITED STATES NAVY ACTIVE DUTY AND RESERVE PERSONNEL

1. Subject matter experts at the Bureau of Medicine and Surgery have compiled the below facts on certain mandatory vaccines for United States (U.S.) Navy Active Duty and Reserve personnel. The information below provides some of the scientific and medical rationale for the vaccine requirements for vaccine-preventable diseases that would otherwise create risk to the readiness of the Force.

2. Coronavirus Disease 2019 (COVID-19)

a. Means of infection and infectivity. Person-to-person transmission via respiratory fluids, composed mainly of respiratory droplets and aerosol particles. Basic reproduction numbers (i.e., the number of people who become ill due to exposure to a single case) are estimated to be 2.8 for the original strain, 4-5 for the Alpha variant, and 5-8 for the Delta variant. In other words, every case of Delta variant COVID-19 can infect 5-8 people if effective countermeasures are not employed.

b. Disease's specific harm to health. COVID-19 symptoms are extremely unpredictable, and range from non-existent (asymptomatic) to death. The most common symptoms are: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion, nausea or vomiting, and diarrhea. These more minor symptoms result in clinic visits, time off work, reduced productivity, possible temporary incapacitation (requiring bed rest). Most serious cases may require hospitalization, the need for oxygen support, and mechanical ventilation. Between 17 December 2020 and 31 August 2021, six Sailors and one Marine have died due to COVID-19; none of them were fully immunized.

(1) The risk of complications from COVID-19 illness is significant. A recent Center for Disease Control and Prevention (CDC) report showed COVID-19 patients had nearly 16 times the risk for myocarditis compared with patients who did not have COVID-19, and this risk was higher in younger age groups.

(2) In addition, there is a significant risk of persistent COVID symptoms after recovery from acute illness, or "long COVID." A recent study found that in patients who had recovered from COVID-19, 87.4% reported persistence of at least one symptom, particularly fatigue and

Subj: DISEASES TARGETED WITH MANDATORY VACCINATIONS FOR UNITED STATES NAVY ACTIVE DUTY AND RESERVE PERSONNEL

dyspnea at an average of 60 days after symptoms onset. Another found that nearly 2/3 of people hospitalized with COVID-19 still had symptoms 6 months later.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. While mild cases may only require isolation and routine symptomatic care, severe cases may rapidly require intensive resources (Role 3 hospital with Intensive Care Unit (ICU) level care and mechanical ventilation) that are not routinely available in a deployed setting. A recent study of over 43,000 COVID-positive patients in England showed the rate of hospitalization within 14 days of testing was 2.2% for the Alpha variant and 2.3% for the Delta variant (74% were unvaccinated).

d. Efficacy/effectiveness of available vaccine(s). In large phase III trials, the Food and Drug Administration (FDA) approved COVID-19 vaccine was shown to have over 94% efficacy at preventing symptomatic COVID-19. For the same vaccine, against the Delta variant in a real world setting, studies show 88% effectiveness against symptomatic disease, to include hospitalization and death. Nationally in the United States, per the CDC, from January through August 2021, the unvaccinated comprised over 99% of all hospitalized COVID patients (over 1.6 million) as well as over 99% of all COVID-19 deaths (over 264,000). There have been zero COVID-19 deaths of Sailors or Marines among those fully immunized, and zero deaths of Sailors or Marines due to vaccination administration.

e. Likelihood of infection if unvaccinated. In a recent (24 Aug 2021) CDC report of over 43,000 SARS-CoV-2 infections in Los Angeles County, California (population approx. 9.6M), over 71% of the infections were unvaccinated and over 85% of hospitalizations were unvaccinated. The same study reported infection and hospitalization rates among unvaccinated persons were 4.9 times and 29.2 times the rates of those for fully vaccinated people, respectively. According to current surveillance data, nearly 87% of hospitalized Department of the Navy (DON) Active Duty COVID-19 cases since 17 December 2020 are among unvaccinated service members. For DON Service members who had COVID-19 since December 2020, surveillance data indicates that hospitalization rates are approximately 500 per 100,000 cases, which is substantially higher than for influenza (see paragraph 2b).

f. Other methods of prevention. For diseases transmitted by respiratory droplets and aerosol particles such as COVID-19, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading COVID-19 have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), wearing facemasks, ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings.

g. Efficacy of non-pharmaceutical interventions. Despite the ability of NPIs to prevent respiratory virus transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates

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(where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(1) Recent studies have shown efficacy of mask wearing to prevent COVID-19. During a COVID-19 outbreak on the *USS THEODORE ROOSEVELT*, persons who wore masks experienced a 70% lower risk of testing positive for SARS-CoV-2 infection. Similar reductions have been reported in case contact investigations when contacts were masked and in household clusters in which household members were masked.

(2) However, in order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

(3) Similarly, NPI such as masks provide measures of community protection, as described above, only while they are in use. Because the scientific and medical communities predict that SARS-CoV-2 will remain in global circulation as an endemic virus, the risk to the Force associated with COVID-19 in unvaccinated personnel may exist in perpetuity.

h. Scientific and Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI, in the absence of vaccination, are not likely to be effective at preventing COVID-19 outbreaks and their resulting impacts on the Navy's mission, especially in the setting of the highly contagious Delta variant. Unlike NPI, vaccination provides its full measure of protection in an enduring capacity, subject to potential boosters as recommended by the FDA. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, vaccination is significantly superior to NPI, and mask wearing, for preventing respiratory infections such as COVID-19, especially when only implemented at the individual level and not by the entire community.

3. Influenza

a. Means of infection. Person-to-person transmission via respiratory droplets. Basic reproduction numbers are estimated to be 0.9-2.1, which means, on average, a person infected with influenza will spread the virus to 1-2 other people, if no additional protective measures are in place.

b. Disease's specific harm to health. Typical symptoms include: fever, cough, sore throat, runny nose, muscle aches, headaches, fatigue, and vomiting / diarrhea (more common in children than adults). This results in clinic visits, time off work, reduced productivity, possible temporary incapacitation (requiring bed rest), and viral shedding, potentially infecting those who come in contact with the person. Hospitalization is rare among young adults with influenza, 3-7 per 100,000 age 18-49. The most common complications of influenza include secondary bacterial

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pneumonia, exacerbations of underlying respiratory conditions, otitis media, laryngotracheobronchitis, and bronchitis. Other complications may include primary pneumonia, encephalitis, aseptic meningitis, transverse myelitis, myocarditis, pericarditis, and Guillain-Barré syndrome.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. For mild cases, rest at home /in quarters (in isolation), oral rehydration, antipyretics, and medications to target symptoms. For severe cases or those with complications, hospitalization (role 3 hospital, minimum) and ICU-level care with mechanical ventilation may be required.

d. Efficacy of available vaccine(s). Although influenza vaccine effectiveness is variable from season to season, since 2003, on average it has been 40% (range 10-60%). In addition, influenza vaccination has been shown in several studies to reduce severity of illness in people who get vaccinated but still get influenza illness. Influenza vaccination can also reduce transmission of the virus, thus protecting family members, co-workers, and other contacts from getting sick. Some of these contacts may be more vulnerable to serious influenza illness, like babies and young children, the elderly, and those with certain chronic health conditions.

e. Periodicity of vaccine boosters. Annual vaccination is required due to changes in the circulating viruses.

f. Likelihood of infection if unvaccinated. If unvaccinated for influenza, a Sailor will have a higher risk of contracting the disease and transmitting it to co-workers. According to the Centers for Disease Control and Prevention, the estimated annual incidence of influenza infection is approximately 8% (varying from 3% to 11%); approximately half of these cases would be symptomatic. However, outbreaks can be explosive, with attack rates exceeding 60% over periods as short as 10 days.

g. Other methods of prevention. For diseases transmitted by respiratory droplets such as influenza, the CDC recommends NPI in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

h. Efficacy of other methods of prevention. Despite the potential for NPIs to prevent respiratory virus transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

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(1) One published observational study out of Japan regarding influenza transmission showed the overall effectiveness of mask wearing was 8.6%, while handwashing showed a negative association (i.e., not protective). A meta-analysis of NPIs to prevent 2009 pandemic influenza infection showed a statistically significant protective effect for regular hand hygiene (38%) and a statistically non-significant protective effect for facemask use.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether other methods of prevention, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing influenza outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as influenza, especially when only implemented at the individual level and not by the entire community.

4. Tetanus

a. Means of infection. The bacteria that causes tetanus, *C. tetani*, usually enters the body through a wound. In the presence of anaerobic conditions, the spores germinate. Toxins are produced and disseminated via blood and lymphatics.

b. Disease's specific harm to health. On the basis of clinical findings, three different forms of tetanus have been described.

(1) The most common type (more than 80% of reported cases) is generalized tetanus. The disease usually presents with a descending pattern. The first sign is trismus, or lockjaw, followed by stiffness of the neck, difficulty in swallowing, and rigidity of abdominal muscles. Other symptoms include elevated temperature, sweating, elevated blood pressure, and episodic rapid heart rate. Spasms may occur frequently and last for several minutes. Spasms continue for 3 to 4 weeks. Complete recovery may take months.

(2) Localized tetanus is an uncommon form of the disease in which patients have persistent contraction of muscles in the same anatomic area as the injury. These contractions may persist for many weeks before gradually subsiding. Localized tetanus may precede the onset of generalized tetanus, but is generally milder.

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(3) Cephalic tetanus is a rare form of the disease, occasionally occurring with otitis media in which clostridium tetani is present in the flora of the middle ear or following injuries to the head. There is involvement of the cranial nerves, especially in the facial area.

(4) Complications of tetanus are common. Laryngospasm or spasm of the muscles of respiration leads to interference with breathing. Fractures of the spine or long bones may result from sustained contractions and convulsions. Hyperactivity of the autonomic nervous system may lead to hypertension or an abnormal heart rhythm. Nosocomial infections are common because of prolonged hospitalization. Secondary infections may include sepsis from indwelling catheters, hospital-acquired pneumonias, and decubitus ulcers. Pulmonary embolism is particularly a problem in persons who use drugs and elderly patients. Aspiration pneumonia is a common late complication of tetanus, found in 50% to 70% of autopsied cases. In recent years, tetanus has been fatal in approximately 11% of reported cases.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. Tetanus cases must be treated in a tertiary care facility with capability to provide long term ICU care and mechanical ventilation. Tetanus immune globulin (TIG) is recommended for persons with tetanus. Intravenous immune globulin (IVIG) contains tetanus antitoxin and may be used if TIG is not available. Because of the extreme potency of the toxin, tetanus disease does not result in tetanus immunity. Active immunization with tetanus toxoid should begin or continue as soon as the person's condition has stabilized.

d. Efficacy of available vaccine(s). Efficacy of the tetanus toxoid has never been studied in a vaccine trial. It can be inferred from protective antitoxin levels that a complete tetanus toxoid series has an efficacy of almost 100%. In the series of 233 cases from 2001–2008, only 7 cases (3%) had received a complete tetanus toxoid series with the last dose within the last 10 years.

e. Periodicity of vaccine boosters. Every 10 years.

f. Likelihood of infection if unvaccinated. While tetanus is rare in the US (averaging 31 cases per year for 2000-2007), nearly all of those cases were in unvaccinated or under-vaccinated individuals. Tetanus is much more common outside the US; in 2015 there were approximately 209,000 infections and about 59,000 deaths globally. As noted above, vaccine efficacy is high, with over 32 times the risk for unvaccinated persons compared to vaccinated.

g. Other methods of prevention. Usual safety measures can help prevent injuries resulting in cuts or puncture wounds from contaminated objects.

h. Efficacy of non-pharmaceutical interventions. At the individual level, such accidents are common and have proven difficult to prevent.

i. Medical opinion on whether other methods of prevention, alone or in concert, will be successful in meeting the compelling government interest. Safety measures alone will not likely be successful in preventing tetanus-prone wounds.

5. Diphtheria

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a. Means of infection. Transmission of diphtheria is most often person-to-person through respiratory droplets. Transmission may also occur from exposure to infected skin lesions or articles soiled with discharges from these lesions. The basic reproduction number is about 2.6.

b. Disease's specific harm to health. This may be a spectrum, but should include worst case scenarios and likelihood of worst case scenarios. Understand that co-morbidities play a significant role in these calculations, and our population tends to lack co-morbidities. The most common form of diphtheria results in a membranous pharyngitis and tonsillitis, with symptoms of fever, sore throat, malaise, and anorexia. While some patients may recover at this point without treatment, others may develop severe disease. The patient may appear quite toxic, but the fever is usually not high. Patients with severe disease may develop marked edema of the submandibular areas and the anterior neck along with lymphadenopathy, giving a characteristic "bull neck" appearance. If enough toxin is absorbed, the patient can develop severe prostration, pallor, rapid pulse, stupor, and coma. Death can occur within 6 to 10 days. Death occurs in 5-10% of diphtheria cases.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. In addition to supportive care, as described for influenza and COVID-19, specific treatments include antitoxin and antibiotics. Diphtheria antitoxin, produced in horses, has been used for treatment of respiratory diphtheria in the United States since the 1890s. Diphtheria antitoxin is available only from CDC, through an Investigational New Drug (IND) protocol. Diphtheria antitoxin does not neutralize toxin that is already fixed to tissues, but it will neutralize circulating toxin and prevent progression of disease.

(1) After a provisional clinical diagnosis of respiratory diphtheria is made, appropriate specimens should be obtained for culture and the patient placed in isolation. Persons with suspected diphtheria should be promptly given diphtheria antitoxin and antibiotics in adequate dosage, without waiting for laboratory confirmation. Respiratory support and airway maintenance should also be provided as needed. Consultation on the use of and access to diphtheria antitoxin is available through the duty officer at CDC's Emergency Operations Center at 770-488-7100.

(2) In addition to diphtheria antitoxin, patients with respiratory diphtheria should also be treated with antibiotics. The disease is usually no longer contagious 48 hours after antibiotics have been given. Elimination of the organism should be documented by two consecutive negative cultures taken 24 hours apart, with the first specimen collected 24 hours after therapy is completed.

d. Efficacy of available vaccine(s). Diphtheria toxoid-containing vaccine has been estimated to have an efficacy of 97%.

e. Periodicity of vaccine boosters. Every 10 years in adults.

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f. Likelihood of infection if unvaccinated. Diphtheria is rare in the U.S. (14 cases were reported between 1996 and 2018), but it is much more common outside the U.S. where vaccination coverage is suboptimal (4,500 cases worldwide in 2015).

g. Other methods of prevention. For diseases transmitted by respiratory droplets such as diphtheria, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination, although widespread vaccination has all but eliminated disease incidence in the U.S. (ex. no cases in 2017 and 2018 according to World Health Organization, which largely eliminated the subsequent need for diphtheria-related NPI in practice). NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

h. Efficacy of non-pharmaceutical interventions. While we are not aware of any studies evaluating the efficacy of NPI specifically for diphtheria, it is likely the effectiveness of most NPI would be similar to that for other infections transmitted by respiratory droplets.

(1) Despite the potential for NPIs to prevent respiratory disease transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing diphtheria outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as diphtheria, especially when only implemented at the individual level and not by the entire community.

6. Pertussis. Note: there is no pertussis vaccine preparation that does not contain tetanus and diphtheria toxoids.

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a. Means of infection. Transmission most commonly occurs person-to-person through contact with respiratory droplets, or by contact with airborne droplets of respiratory secretions. Transmission occurs less frequently by contact with an infected person's freshly contaminated articles. The basic reproduction number is about 5.5.

b. Disease's specific harm to health. The clinical course of pertussis is divided into three stages: catarrhal (with symptoms similar to the common cold lasting 1-2 weeks), paroxysmal (with more severe cough and paroxysms of numerous rapid coughs lasting 1-6 weeks), and convalescent (with gradual recovery over weeks to months). The most common complication and cause of death is secondary bacterial pneumonia, occurring in 13.2% of cases. Between 2000 and 2017, 307 deaths from pertussis were reported to CDC, mostly in children. Adults may also develop complications of pertussis, such as difficulty sleeping, urinary incontinence, pneumonia, rib fracture, syncope, and weight loss

c. Treatment required and level of medical treatment facility capable of delivering that treatment. Varying levels of supportive management are required, depending on severity of disease, as with influenza and COVID-19. Antibiotics are of some value if administered early (i.e., during the first 1 to 2 weeks of cough before coughing paroxysms begin).

d. Efficacy of available vaccine(s). Diphtheria, Tetanus, and Pertussis (DTaP) vaccine efficacy ranged from 80% to 85%, with overlapping confidence intervals.

e. Periodicity of vaccine boosters. Every 10 years.

f. Likelihood of infection if unvaccinated. Reported pertussis incidence has been gradually increasing in the U.S. since the late 1980s and early 1990s, and large epidemic peaks in disease have been observed since the mid-2000s. A total of 48,277 pertussis cases were reported in 2012, the largest number reported since the mid-1950s. Recent outbreaks of pertussis in the U.S. were due to low vaccination rates with large numbers of vaccine refusals (over 75% in one cluster) based on nonmedical reasons. The disease is more common outside the U.S.; an estimated 16.3 million people worldwide were infected in 2015, with 58,700 deaths.

g. Other methods of prevention, such as non-pharmaceutical interventions. For diseases transmitted by respiratory droplets such as pertussis, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

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h. Efficacy of non-pharmaceutical interventions. While we are not aware of any studies evaluating the efficacy of NPI specifically for pertussis, it is likely the effectiveness of most NPI would be similar to that for other infections transmitted by respiratory droplets.

(1) Despite the potential for NPIs to prevent respiratory disease transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing pertussis outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as pertussis, especially when only implemented at the individual level and not by the entire community.

7. My point of contact is (b) (6), MC, USN, Preventive Medicine, who can be reached at (b) (6) or (b) (6)@mail.mil.

(b) (6)



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1730
Ser N13/306
17 Nov 21

MEMORANDUM

From: Director, Military Personnel Plans and Policy (N13)
To: Deputy Chief of Naval Operations (Manpower, Personnel, Training and Education) (N1)

Subj: RELIGIOUS ACCOMMODATION (RA) REQUESTS FROM SAILORS SEEKING
IMMUNIZATION WAIVERS

Ref: (a) 42 U.S.C. §2000bb-1
(b) DoD Instruction 1300.17 of 1 Sep 20
(c) SECNAVINST 1730.8B Ch-1
(d) BUPERSINST 1730.11A
(e) MILPERSMAN 1730-020
(f) ASN (M&RA) memo of 6 Jun 13
(g) BUMEDINST 6230.15B
(h) OPNAVINST 1300.20

Encl: (1) CHBUMED ltr 6320 Ser M44/21UM401 of 22 Sep 21
(2) CDC Information of 15 Sep 21

1. Purpose. This memorandum provides analysis of the least restrictive means for achieving the Navy's compelling government interest in preventing the spread of diseases to support mission accomplishment, including military readiness, unit cohesion, good order and discipline, or health and safety, at the individual, unit, and organizational levels. This includes reducing vaccine preventable diseases in individual Sailors and preventing the spread of vaccine-preventable communicable diseases among Sailors. The compelling government interest is not in dispute and is addressed here only briefly. Navy leaders have determined that requiring all Navy Service Members ("Sailors") to be vaccinated against certain diseases is the least restrictive means of achieving that compelling government interest. This memorandum explains the analysis behind that determination and addresses the risk to mission accomplishment inherent in deviating from requiring vaccination of all Sailors.

2. References. Reference (a), the Religious Freedom Restoration Act (RFRA), prohibits the U.S. Government from substantially burdening a person's exercise of a sincerely held religious belief unless the restriction, as applied to the specific person, is in furtherance of a compelling government interest and is the least restrictive means of furthering that compelling government interest. References (b) through (d) establish procedures for Sailors seeking religious accommodations (RAs). Reference (e) provides amplifying details on RA requests for

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immunization waivers.¹ Reference (f) designates the Deputy Chief of Naval Operations (Manpower, Personnel, Training, and Education) (DCNO N1) as the U.S. Navy adjudication authority for RAs, including requests for immunization waivers. In cases where DCNO N1 has disapproved a request, and the member submits an appeal, the adjudication authority rests with the Chief of Naval Operations (CNO), in line with references (c) and (d).

Compelling Government Interest

3. The Navy's compelling government interest in preventing spread of diseases to support mission accomplishment, including military readiness, unit cohesion, good order and discipline, or health and safety, at the individual, unit, and organizational levels is addressed in enclosures (1) and (2), along with the Bureau of Medicine and Surgery (BUMED) endorsement on each RA request seeking an immunization waiver. Vaccine-preventable diseases cause severe illness, long-term health effects, and death, interfere with the ability of Sailors to accomplish the Navy's mission at the individual, unit, and organizational levels, decrease the overall health of the force, and place additional strain on medical resources. Spread of communicable diseases among Sailors who live and work in tight quarters aboard ships or in communal environments while deployed, or who live or work in close proximity to others in the shore establishment, have the potential to cause mission failure when one or more personnel become too sick to effectively do their jobs. Logistical challenges inherent in moving personnel to and from deployed ships and other deployed environments make it difficult to quickly evacuate sick personnel and replace them with healthy personnel who are adequately trained and ready at a moment's notice. The Navy's lean manning methodology to operate successfully during prolonged budget constraints further limits the quick replacement of personnel in deployed environments. In the case of personnel operating in foreign locations, the spread of communicable diseases from U.S. Navy personnel to host-nation personnel would have a detrimental impact on U.S. foreign relations, especially if the illness was viewed as preventable. Additionally, Navy ships have limited medical and long-term placement capabilities. If even one Sailor infected with a communicable disease requires treatment beyond the capabilities of a ship's medical department, or if multiple Sailors must be placed in critical care, a decision will have to be made whether the ship may have to abandon its mission and transit to a location that offers more adequate treatment. Foreign medical facilities may also refuse to accept a U.S. Navy patient infected with a communicable disease, requiring the ship to transit farther—potentially thousands of miles, exacerbating an already difficult situation. Foreign ports may refuse entry to a Navy ship with a communicable disease onboard. The ship may be denied free pratique and not allowed to enter

¹ As of the date of this memorandum, reference (e) is out of conformity with reference (b), rendering many provisions of reference (e) invalid. For example, a commanding officer (CO) cannot order a Sailor with an RA approved by DCNO N1 to receive a vaccine waived by the RA because reference (b) allows rescission of an RA only by an official at the level in the chain of command that granted the RA. In other words, if DCNO N1 grants an RA, then only DCNO N1 (or someone senior to DCNO N1) may rescind the RA. The only exception is for exigent circumstances amounting to a life-threatening or mission critical emergency. (For example, a CO could order a Sailor to shave a religious beard approved by DCNO N1 to get an effective seal on a gasmask in response to credible intelligence of an imminent chemical weapons attack.) Because immunizations do not provide immediate immunity, it is unlikely a CO would have bona fide exigent circumstances to order a Sailor to receive an immunization where a RA waived the requirement for a Sailor to receive that immunization. *See, e.g.*, CDC guidance on the COVID-19 Delta variant, available online at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html?s_cid=11617:delta%20variant%20covid:sem.ga:p:RG:GM:gen:PTN.Grants:FY22.

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port or allow personnel to embark or disembark. While the consequences of disease are most severe in deployed ships, they are nevertheless compelling in Navy billets ashore. A significant portion of the shore establishment is collocated with the operating forces and supports those forces with readiness activities such as maintenance, technical support, training, and medical care. Many shore duty billets require in-person work in enclosed office spaces where spread of disease is possible. Even Sailors who might be able to work in isolation a large portion of the time have certain military duties, such as medical exams, physical fitness tests, urinalysis, and ad hoc meetings. Finally, because the Navy prioritizes manning on deployable units first, many shore units are manned only at or *below* the planned manning levels, magnifying the impact of preventable sickness on mission accomplishment.

4. There are specific compelling government interest concerns for each required vaccination.

a. COVID-19 can cause severe illness and death in young, otherwise healthy individuals, including the eight active duty Sailors and two active duty Marines killed by the disease as of 26 October 2021. All ten of these personnel were not fully vaccinated. No deaths caused by COVID-19 have been reported in fully vaccinated service members, active or reserve. The highly transmissible Delta variant is of particular concern and is more transmissible than other variants.² As reported in enclosure (1), studies of available mRNA vaccines, including the FDA-approved Comirnaty vaccine manufactured by Pfizer, have shown an 88% efficacy rate against the Delta variant. Further, enclosure (1) discusses a recent study showing over 71% of recent COVID infections occurring in unvaccinated individuals and more than 85% of hospitalizations in unvaccinated individuals. For people evaluated in the study, the hospitalization rate of unvaccinated individuals was more than 29 times that of fully vaccinated individuals. While anyone can spread COVID-19, fully-vaccinated people will likely spread the virus for less time and to fewer people than unvaccinated people.

b. In the case of Sailors, including those in the accession pipeline, who are requesting waiver of all future immunizations, the following considerations apply to vaccinations required by reference (g) for all Sailors, regardless of location:

(1) Every year, the influenza vaccine is required for all Sailors who do not have a medical or administrative exemption. As explained in enclosure (1), the spread of influenza will deprive the Navy of medical resources and commands of personnel needed to accomplish the mission while those personnel recover and place additional strain on those who must augment to fill the sick Sailors' positions. In severe cases, personnel infected with influenza require hospitalization. Influenza outbreaks can be explosive, with the potential to incapacitate many Sailors assigned to one command.

(2) Every 10 years, the Tdap (tetanus, diphtheria, pertussis) or Td (tetanus, diphtheria) vaccine is required for all Sailors who do not have a medical or administrative exemption. Enclosure (1) explains the specific, debilitating consequences of infection with each of the diseases prevented by the highly effective Tdap vaccine. For example, the Tdap vaccine is almost 100% effective at preventing tetanus, a disease with an 11% mortality rate. Infection

² Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science" 26 Aug 2021.

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with tetanus would prevent a Sailor from performing their individual mission and affect mission accomplishment at the unit level, and recovery takes months. Tdap is 97% effective at preventing diphtheria, which is common in some areas outside of the United States. Before the development of a vaccine, diphtheria was a leading cause of death among children in the United States. Diphtheria has a 5 to 10% mortality rate. Tdap is 80 to 85% effective at preventing pertussis, a disease that causes bacterial pneumonia in more than 13% of cases. A Sailor infected with any of the diseases that Tdap successfully prevents could be inhibited from accomplishing their mission for months, and death is possible.

c. A number of vaccines are required by reference (g) for deployment and/or overseas assignment. These location-specific vaccinations protect Sailors against local threats, including anthrax, Japanese encephalitis, yellow fever, typhoid fever, and smallpox. The Geographic Combatant Command (GCC) establishes these requirements, and the GCC Command Surgeon serves as the approval authority for waivers of the GCC requirements. The following information is from the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov) and other public sources:

(1) The CDC website reports the anthrax vaccine is 93% effective. Anthrax inhalation³ is almost always fatal in unvaccinated individuals who do not receive immediate treatment, and even with aggressive treatment, anthrax inhalation kills 45% of unvaccinated patients.

(2) The World Health Organization website (www.who.int) indicates the Japanese encephalitis vaccine is more than 99% effective. The CDC website indicates that, although Japanese encephalitis is rare, one in four cases is fatal.

(3) According to the CDC, typhoid fever is common in developing nations, with as many as 21 million cases occurring each year, mostly in South Asian and Southeast Asian nations frequented by deployed Sailors. Because antibiotic treatments are effective against the disease, only about 200,000 of these patients die each year. However, the CDC reports a growing incidence of typhoid fever resistant to antimicrobial drugs. The disease can be spread both by contaminated food and water and by contact with infected persons.

(4) The CDC website reports that, although yellow fever infection is rare, 30 to 60% of those who develop severe yellow fever disease die.

(5) The smallpox vaccination is so effective that it eradicated a disease the World Health Organization characterizes on its website as “one of the most devastating diseases known to humanity.” Before mass vaccination, millions of people were killed or disfigured by the disease. It is believed that smallpox no longer exists in nature. However, the CDC reports, “There is a credible concern that in the past some countries made the virus into weapons, which may have fallen into the hands of terrorists or other people with criminal intentions.”

³ The anthrax immunization requirement in reference (g) is designed to protect personnel against weaponized anthrax. Research into the harm of anthrax has been possible because of exposure to naturally occurring anthrax.

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d. Requiring new accessions to the Navy to have completed or receive traditionally childhood immunizations is also critical to mission accomplishment. Although an individual breakdown of these required immunizations is beyond the scope of this memorandum, it is addressed in Appendix D to reference (g). Examples of diseases for which new accessions must receive immunizations, if not previously immunized, include adenovirus, polio, measles, mumps, rubella, hepatitis A and B, and varicella.

Non-Pharmaceutical Interventions (NPIs)

5. BUMED reports that the CDC recommends use of NPIs in conjunction with vaccination to stem the spread of diseases transmitted by respiratory droplets, including COVID-19, influenza, and pertussis. Specifically, the CDC recommends respiratory hygiene (covering mouth and nose while coughing or sneezing), avoiding touching the face, frequent hand washing with soap for at least 20 seconds, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. BUMED reports that masking is appropriate in some circumstances, as well as social distancing of six feet or more to stem the spread of certain respiratory illnesses. Unfortunately, BUMED reports that there is very limited data available on the effectiveness of NPIs. This makes it difficult to compare scientifically proven efficacy rates of NPIs not accompanied by vaccination to the efficacy rates of vaccination or vaccination with NPI usage. BUMED states that NPIs are known to be more effective at preventing spread of disease when implemented as community-wide mandates than when implemented by one individual. This factor is key in the determination that NPIs are not sufficient alone to protect Sailors from the risks imposed by COVID-19 and other communicable diseases, and ultimately to ensure the Navy's ability to achieve mission accomplishment, including readiness, unit cohesion, good order and discipline, or health and safety, at the individual, unit, and organizational levels.

Least Restrictive Means

6. COVID-19. As discussed below, mandatory immunization of all Sailors against COVID-19 is the least restrictive means of achieving the Navy's compelling government interest in reducing to zero any preventable impairment to mission accomplishment, including readiness, health, and safety, at the individual, unit, and organizational levels in the operating forces and shore establishment.

a. Health and Safety. The Navy has not identified any means equally or more effective than mandatory immunization against COVID-19 to ensure the health and safety of Sailors, including a Sailor who seeks a religious accommodation from the mandatory COVID-19 vaccination requirement. As discussed in paragraph 4 and enclosure (1), the scientific data shows that a fully vaccinated Sailor is at far less risk of serious illness or death in the event of a "breakthrough COVID-19 case." To date, not one fully vaccinated Sailor has died from COVID-19. Among those Sailors who are fully vaccinated, only 1.7 percent contracted a "breakthrough case" between 17 December 2020 and 26 October 2021. In the same timeframe, 23.3% of unvaccinated active duty Sailors experienced COVID-19 infections. Regardless of whether a Sailor is assigned to the operating forces or the shore establishment, mandatory COVID-19

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immunization is the least restrictive means to ensure readiness and health and safety at the individual, unit, and organizational levels of the Navy.

b. Restriction of Movement (ROM). For more than a year during the COVID-19 pandemic, the Navy imposed stringent restrictions across the force in every location to limit the activities and behaviors of Sailors assigned to both shore and operational units to keep them and the force healthy. Almost all quality-of-life port visits were cancelled, and Sailors were ordered to quarantine within the bubbles of their ships for two weeks before getting underway. (This quarantine is referred to as restriction of movement (ROM).) Ashore, Sailors were ordered to forego haircuts, prohibited from dining in restaurants, and restricted from recreation to a far greater degree than the general public. COVID-19 vaccinations have allowed the lives of many Sailors to start getting back to normal. ROM periods have been relaxed for fully vaccinated Sailors and for crews of ships with very high vaccination rates.

(1) In the best of times, Navy life is hard on Sailors' family and social lives. There are many challenges that our Sailors face that are unique to naval service. In the case of an operational unit preparing to deploy, additional stress is expected as the Sailors must balance the demands of work and home. Long periods of time underway are known to strain the emotional and psychological wellbeing of Sailors. Adding additional periods of time isolated from family, friends, and society at large due to ROM requirements has exacerbated these concerns and negatively impacted readiness. This concern is equally as important on shore duty, which the Navy relies on as a periodic respite from the stress of sea duty. However, the ROM periods were justified as a necessary mitigation technique to avoid COVID-19 infections that could interfere with mission accomplishment, and were largely effective.

(2) It is not safe for a vessel to deploy with even one unvaccinated Sailor unless the entire crew goes through a ROM period and port visits continue to be cancelled. As explained in enclosure (2), "Vaccinated people can still become infected and have the potential to spread the virus to others, although at much lower rates than unvaccinated people." Further, unvaccinated personnel are significantly more likely to require hospitalization than vaccinated individuals with breakthrough infections. Taken together, these two facts make clear that imposing ROM measures only on unvaccinated Sailors would be insufficient to protect against risk of mission failure inherent in allowing unvaccinated Sailors to go to sea because an unvaccinated Sailor can be exposed to COVID-19 via a breakthrough case in a vaccinated shipmate who was not required to ROM. There is an appreciable risk that acquiring treatment for one unvaccinated Sailor would require a ship to abandon its mission and transit to a location with a shore-based medical facility able and willing to care for the COVID-19 patient. Some countries may deny a Navy ship free pratique, that is entry into port and disembarkation or embarkation of personnel, if there is a communicable disease onboard, or host-nation medical facilities may be unwilling or unable to accept unvaccinated U.S. COVID-19 patients, which could lead to a ship abandoning its mission and transiting thousands of miles in an effort to save a life, with negative impact on unit and organizational mission accomplishment.

(3) Continuing to require 14-day ROM periods for all Sailors and canceling future port visits is not a sustainable approach. Port visits serve as a much-needed venue to acquire parts, mail, fresh food, and a quality of life respite for Sailors. This approach would involve a very

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high cost to the emotional and psychological wellbeing of other Sailors, decreasing the readiness of the entire crew. Further, a deployment with no port visits that locks Sailors to their ships weeks before getting underway will likely lead to diminished job satisfaction and discourage Sailor recruitment and retention. While this tradeoff was temporarily acceptable during the COVID-19 pandemic before vaccinations were available, use of ROM as permanent means of accomplishing the Navy's compelling governmental interest in mission accomplishment is untenable.

c. Other available NPIs, both those identified by BUMED and others discussed by recent news articles, are insufficient to protect unvaccinated Sailors aboard U.S. Navy ships for the following reasons:

(1) Masking. The Navy can require all Sailors to wear masks, but full-time tight quarters on a ship severely limits its effectiveness, as does communal living in barracks or working in close quarters ashore. Aboard ship, unvaccinated Sailors will have to eat, sleep, shower, and brush their teeth in the same spaces as vaccinated Sailors who have gone on liberty among the general public and been excused from ROM requirements.

(2) Ventilation. U.S. Navy ships have almost no windows, and fresh air circulation is limited by steel construction that includes collective protection systems (CPS) in place to seal off areas of ships for protection against chemical, biological, or radiological weapons attacks. During training drills, the ship will secure ventilation to demonstrate the required actions in the case of a damage-control emergency.

(3) Social distancing. Maintaining a social distance for Sailors on U.S. Navy ships is impossible. Narrow passageways do not allow for Sailors to maintain social distances when transiting a ship. Almost all enlisted berthing compartments feature three-foot by six-foot bunks, referred to as "racks," that are stacked three high and have only narrow passages between rows. Enlisted berthing compartments have as few as 12 and as many 210 personnel sleeping in the same space, where there are generally racks for six Sailors in every thousand cubic yards. Sailors in larger berthing compartments are never alone in the head when they shower or brush their teeth while underway because a head the size of a studio apartment can be shared among 200 or more personnel. In the case of fast-attack submarines, populations are smaller, but some Sailors have to take turns sleeping in shared racks. Most officers share small staterooms with between one and five of their peers, and tiny heads are often shared between many officers. In addition to sleeping and engaging in personal hygiene, meals are also uncondusive to use of NPIs. Sailors are fortunate if they can keep their elbows and knees six inches from those around them while eating on mess decks. The wardrooms where officers dine are only slightly more spacious. Extending meal hours to allow fewer people to dine at a time would unfairly burden Culinary Specialists and Food Service Attendants, who are already known in the Navy for having some of the longest and most arduous working hours, and would not be sustainable. There are few alternative locations for Sailors to eat on ships, and allowing Sailors to take meals out of areas designated for eating has the potential to invite rodent and insect infestations. Even if the recommended 6-foot spacing were possible, it may not be adequate aboard ships due to the ventilation characteristics of the vessel. Social distancing may be more tenable ashore, but is highly dependent on the type of work a Sailor does and the configuration of their workspace(s).

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(4) Cleanliness. As hard as Sailors work to keep their ships clean, safe transit up and down ladders and through watertight doors requires everyone to touch all of the same handrails and handles frequently. Further, although Sailors can be reminded to use hand sanitizer, frequent handwashing is not generally possible because Sailors have to transit up and down ladders, with those shared handrails, to get between their workspaces and the heads in which they can wash their hands.

(5) Self Quarantine. It is very difficult to quarantine individual Sailors onboard an underway U.S. Navy ship because there are limited extra spaces. On smaller ships, medical divisions operate out of one space. Even on larger ships, medical departments have limited space to quarantine or isolate personnel. Further, vaccinated or unvaccinated Sailors with COVID-19 infections may be asymptomatic or may suffer such mild symptoms that they do not realize they are contagious until after an unvaccinated shipmate has become infected.

d. Because shipboard environments significantly limit the effectiveness of all NPIs, and because even one serious COVID-19 infection can pull a ship off station resulting in mission failure at the unit and possibly organizational levels, immunization of all Sailors against COVID-19 is absolutely necessary and is the least restrictive means of achieving the Navy's compelling government interest in preventing spread of communicable disease to ensure mission accomplishment.

e. Although the drawbacks of NPIs are most acute shipboard, the NPIs still do not meet the compelling government interest ashore. Ashore, a Sailor is in more frequent contact with the public, and has significant interaction outside the Navy workplace. Therefore, the opportunity to be in close contact with an infected person is actually greater. Additionally, none of the NPI, individually or together, is sufficiently effective to meet the Navy's compelling government interest.

7. Other Respiratory Illnesses. NPIs are ineffective at stemming the spread of other respiratory illnesses aboard ships for the same reasons NPIs are ineffective against COVID-19. For many years, U.S. Navy units have been spared serious outbreaks of influenza, diphtheria, and pertussis by widespread vaccination among the U.S. population and among Sailors in particular. Unfortunately, vaccine hesitancy in recent years has allowed for an uptick in communicable disease in the American public. Due to the tight quarters aboard ships discussed above, infection with one of these respiratory illnesses by an unvaccinated Sailor is likely to spread quickly and incapacitate other unvaccinated Sailors. Because of lean shipboard manning and the possible need to abandon a mission to seek higher-level medical care for an infected Sailor, one of these diseases could lead to mission ineffectiveness or mission failure. Therefore, immunization is the least restrictive means available to achieve the Navy's compelling government interest in reducing to zero any preventable impairment to mission accomplishment because it helps to prevent the spread of these diseases through individual infections or community spread of these diseases.

8. Mosquito-Borne Illnesses. Japanese encephalitis and yellow fever are transmitted by mosquitos. Sailors traveling to or stationed in parts of the world where one of these diseases is

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endemic can protect themselves through very careful use of mosquito repellents. Unfortunately, there is risk in forgetting to apply repellent or getting bitten immediately after showering but before having an opportunity to apply repellent. Also, the potential harm from these diseases is great, including risk of death. Because NPIs are significantly less reliable than immunization, NPIs alone are not sufficient to prevent spread of mosquito-borne illnesses, and immunization is the least restrictive means available for preventing the spread of these diseases to allow for mission accomplishment. These vaccines are required only of Sailors who are likely to be deployed to areas of the world where the diseases are common.

9. Contamination-Related Illnesses. Typhoid fever is usually caused by consumption of contaminated food or water or by close contact with an infected person, and is common in certain parts of the world. Tetanus is caused by bacterium spores entering the body through broken skin. Ships, piers, and shipyards are industrial environments in which any scrape or scratch could cause a tetanus infection for an unvaccinated Sailor. There are no NPIs to prevent the spread of these illnesses, and risk of harm is great. Therefore, immunization is the least restrictive means available for preventing harm from these diseases to allow for mission accomplishment. The Typhoid vaccine is required only of Sailors who are likely to be deployed to areas of the world where the disease is common.

10. Weaponized Disease. Anthrax and smallpox present a threat to Sailors only if weaponized by an enemy or terrorist organization. Immunization is the only measure to prevent either of these diseases. Therefore, immunization is the least restrictive means for preventing harm from these diseases to allow for mission accomplishment.

11. Sailors on Shore. The U.S. Navy budget, end-strength limits, and personnel strategy dictate that every Sailor must be deployable and do not allow for keeping Sailors on the payroll who are unable to deploy. This policy is documented by reference (h), OPNAVINST 1300.20, "Deployability Assessment and Assignment Program," which requires administrative separation processing or referral to the Disability Evaluation System for any Sailor who is undeployable for 12 months or longer. It is very rare for a Sailor to be retained in a permanent limited duty status because the Navy needs Sailors who can go to sea or otherwise deploy.

a. Authorizing Sailors assigned to shore duty or the Navy Reserve to forego required immunizations is untenable because of the need for Sailors to be ready to deploy at a moment's notice. Even a Sailor on shore duty pending retirement can be called up to deploy when necessary to achieve mission requirements. Presidential recall under Title 10, U.S. Code, authorizes the Reserve Component to mobilize in a variety of geographic locations, including overseas.

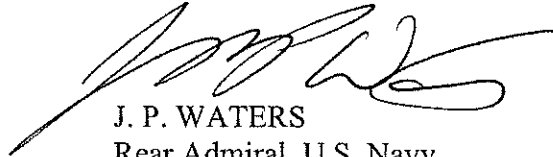
b. Immunity is not instantaneous. Every vaccination requires time to confer immunity. In the case of the now-mandatory COVID-19 Pfizer vaccination, immunity is achieved five weeks after the first dose (two weeks after the second dose). For a short-notice mission, whether in response to tasking or to relieve other Sailors impacted by injury or illness, mission failure could result if Navy leaders are required to wait five weeks to safely deploy Sailors waived from vaccination requirements because of assignment to shore duty.

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c. Even one unvaccinated Sailor, after contracting COVID-19, affects mission accomplishment at the individual level, and can infect dozens of other Sailors, exacerbating the problem of shore and Reserve deployability. Vaccines for worldwide-deployable Sailors throughout the force (shore and sea) constitute the least restrictive means of ensuring a ready, agile fighting force.

d. In addition, individual Sailors and units ashore perform important duties in support of the Navy mission. As an “optimally” manned organization, the Navy relies on each Sailor and unit to be fully ready to accomplish their mission because there is often no backup person with the same skillset. Therefore, even a Sailor who is not subject to imminent deployment must be ready, healthy, and safe to perform their shore-based mission.

12. To achieve its mission, the Navy relies on all Sailors receiving required immunizations, except where the health risk of vaccination exceeds the benefits of vaccination, such as in the case of life-threatening allergies to vaccine components. The small group of Sailors who have temporary medical exemptions and the very small group with permanent medical exemptions are at higher risk for infection, hospitalization, and death, making it even more important that those who work with and around them to be vaccinated. Deviating from this standard will put the mission, our medical capabilities, our Sailors, and their families at risk.



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IN REPLY REFER TO

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Ser M44/21UM401

22 Sep 21

From: Chief, Bureau of Medicine and Surgery

To: Deputy Chief of Naval Operations, Manpower, Personnel, Training, and Education (N1)

Subj: DISEASES TARGETED WITH MANDATORY VACCINATIONS FOR UNITED STATES NAVY ACTIVE DUTY AND RESERVE PERSONNEL

1. Subject matter experts at the Bureau of Medicine and Surgery have compiled the below facts on certain mandatory vaccines for United States (U.S.) Navy Active Duty and Reserve personnel. The information below provides some of the scientific and medical rationale for the vaccine requirements for vaccine-preventable diseases that would otherwise create risk to the readiness of the Force.

2. Coronavirus Disease 2019 (COVID-19)

a. Means of infection and infectivity. Person-to-person transmission via respiratory fluids, composed mainly of respiratory droplets and aerosol particles. Basic reproduction numbers (i.e., the number of people who become ill due to exposure to a single case) are estimated to be 2.8 for the original strain, 4-5 for the Alpha variant, and 5-8 for the Delta variant. In other words, every case of Delta variant COVID-19 can infect 5-8 people if effective countermeasures are not employed.

b. Disease's specific harm to health. COVID-19 symptoms are extremely unpredictable, and range from non-existent (asymptomatic) to death. The most common symptoms are: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion, nausea or vomiting, and diarrhea. These more minor symptoms result in clinic visits, time off work, reduced productivity, possible temporary incapacitation (requiring bed rest). Most serious cases may require hospitalization, the need for oxygen support, and mechanical ventilation. Between 17 December 2020 and 31 August 2021, six Sailors and one Marine have died due to COVID-19; none of them were fully immunized.

(1) The risk of complications from COVID-19 illness is significant. A recent Center for Disease Control and Prevention (CDC) report showed COVID-19 patients had nearly 16 times the risk for myocarditis compared with patients who did not have COVID-19, and this risk was higher in younger age groups.

(2) In addition, there is a significant risk of persistent COVID symptoms after recovery from acute illness, or "long COVID." A recent study found that in patients who had recovered from COVID-19, 87.4% reported persistence of at least one symptom, particularly fatigue and

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dyspnea at an average of 60 days after symptoms onset. Another found that nearly 2/3 of people hospitalized with COVID-19 still had symptoms 6 months later.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. While mild cases may only require isolation and routine symptomatic care, severe cases may rapidly require intensive resources (Role 3 hospital with Intensive Care Unit (ICU) level care and mechanical ventilation) that are not routinely available in a deployed setting. A recent study of over 43,000 COVID-positive patients in England showed the rate of hospitalization within 14 days of testing was 2.2% for the Alpha variant and 2.3% for the Delta variant (74% were unvaccinated).

d. Efficacy/effectiveness of available vaccine(s). In large phase III trials, the Food and Drug Administration (FDA) approved COVID-19 vaccine was shown to have over 94% efficacy at preventing symptomatic COVID-19. For the same vaccine, against the Delta variant in a real world setting, studies show 88% effectiveness against symptomatic disease, to include hospitalization and death. Nationally in the United States, per the CDC, from January through August 2021, the unvaccinated comprised over 99% of all hospitalized COVID patients (over 1.6 million) as well as over 99% of all COVID-19 deaths (over 264,000). There have been zero COVID-19 deaths of Sailors or Marines among those fully immunized, and zero deaths of Sailors or Marines due to vaccination administration.

e. Likelihood of infection if unvaccinated. In a recent (24 Aug 2021) CDC report of over 43,000 SARS-CoV-2 infections in Los Angeles County, California (population approx. 9.6M), over 71% of the infections were unvaccinated and over 85% of hospitalizations were unvaccinated. The same study reported infection and hospitalization rates among unvaccinated persons were 4.9 times and 29.2 times the rates of those for fully vaccinated people, respectively. According to current surveillance data, nearly 87% of hospitalized Department of the Navy (DON) Active Duty COVID-19 cases since 17 December 2020 are among unvaccinated service members. For DON Service members who had COVID-19 since December 2020, surveillance data indicates that hospitalization rates are approximately 500 per 100,000 cases, which is substantially higher than for influenza (see paragraph 2b).

f. Other methods of prevention. For diseases transmitted by respiratory droplets and aerosol particles such as COVID-19, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading COVID-19 have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), wearing facemasks, ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings.

g. Efficacy of non-pharmaceutical interventions. Despite the ability of NPIs to prevent respiratory virus transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates

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(where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(1) Recent studies have shown efficacy of mask wearing to prevent COVID-19. During a COVID-19 outbreak on the *USS THEODORE ROOSEVELT*, persons who wore masks experienced a 70% lower risk of testing positive for SARS-CoV-2 infection. Similar reductions have been reported in case contact investigations when contacts were masked and in household clusters in which household members were masked.

(2) However, in order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

(3) Similarly, NPI such as masks provide measures of community protection, as described above, only while they are in use. Because the scientific and medical communities predict that SARS-CoV-2 will remain in global circulation as an endemic virus, the risk to the Force associated with COVID-19 in unvaccinated personnel may exist in perpetuity.

h. Scientific and Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI, in the absence of vaccination, are not likely to be effective at preventing COVID-19 outbreaks and their resulting impacts on the Navy's mission, especially in the setting of the highly contagious Delta variant. Unlike NPI, vaccination provides its full measure of protection in an enduring capacity, subject to potential boosters as recommended by the FDA. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, vaccination is significantly superior to NPI, and mask wearing, for preventing respiratory infections such as COVID-19, especially when only implemented at the individual level and not by the entire community.

3. Influenza

a. Means of infection. Person-to-person transmission via respiratory droplets. Basic reproduction numbers are estimated to be 0.9-2.1, which means, on average, a person infected with influenza will spread the virus to 1-2 other people, if no additional protective measures are in place.

b. Disease's specific harm to health. Typical symptoms include: fever, cough, sore throat, runny nose, muscle aches, headaches, fatigue, and vomiting / diarrhea (more common in children than adults). This results in clinic visits, time off work, reduced productivity, possible temporary incapacitation (requiring bed rest), and viral shedding, potentially infecting those who come in contact with the person. Hospitalization is rare among young adults with influenza, 3-7 per 100,000 age 18-49. The most common complications of influenza include secondary bacterial

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pneumonia, exacerbations of underlying respiratory conditions, otitis media, laryngotracheobronchitis, and bronchitis. Other complications may include primary pneumonia, encephalitis, aseptic meningitis, transverse myelitis, myocarditis, pericarditis, and Guillain-Barré syndrome.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. For mild cases, rest at home /in quarters (in isolation), oral rehydration, antipyretics, and medications to target symptoms. For severe cases or those with complications, hospitalization (role 3 hospital, minimum) and ICU-level care with mechanical ventilation may be required.

d. Efficacy of available vaccine(s). Although influenza vaccine effectiveness is variable from season to season, since 2003, on average it has been 40% (range 10-60%). In addition, influenza vaccination has been shown in several studies to reduce severity of illness in people who get vaccinated but still get influenza illness. Influenza vaccination can also reduce transmission of the virus, thus protecting family members, co-workers, and other contacts from getting sick. Some of these contacts may be more vulnerable to serious influenza illness, like babies and young children, the elderly, and those with certain chronic health conditions.

e. Periodicity of vaccine boosters. Annual vaccination is required due to changes in the circulating viruses.

f. Likelihood of infection if unvaccinated. If unvaccinated for influenza, a Sailor will have a higher risk of contracting the disease and transmitting it to co-workers. According to the Centers for Disease Control and Prevention, the estimated annual incidence of influenza infection is approximately 8% (varying from 3% to 11%); approximately half of these cases would be symptomatic. However, outbreaks can be explosive, with attack rates exceeding 60% over periods as short as 10 days.

g. Other methods of prevention. For diseases transmitted by respiratory droplets such as influenza, the CDC recommends NPI in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

h. Efficacy of other methods of prevention. Despite the potential for NPIs to prevent respiratory virus transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

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(1) One published observational study out of Japan regarding influenza transmission showed the overall effectiveness of mask wearing was 8.6%, while handwashing showed a negative association (i.e., not protective). A meta-analysis of NPIs to prevent 2009 pandemic influenza infection showed a statistically significant protective effect for regular hand hygiene (38%) and a statistically non-significant protective effect for facemask use.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether other methods of prevention, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing influenza outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as influenza, especially when only implemented at the individual level and not by the entire community.

4. Tetanus

a. Means of infection. The bacteria that causes tetanus, *C. tetani*, usually enters the body through a wound. In the presence of anaerobic conditions, the spores germinate. Toxins are produced and disseminated via blood and lymphatics.

b. Disease's specific harm to health. On the basis of clinical findings, three different forms of tetanus have been described.

(1) The most common type (more than 80% of reported cases) is generalized tetanus. The disease usually presents with a descending pattern. The first sign is trismus, or lockjaw, followed by stiffness of the neck, difficulty in swallowing, and rigidity of abdominal muscles. Other symptoms include elevated temperature, sweating, elevated blood pressure, and episodic rapid heart rate. Spasms may occur frequently and last for several minutes. Spasms continue for 3 to 4 weeks. Complete recovery may take months.

(2) Localized tetanus is an uncommon form of the disease in which patients have persistent contraction of muscles in the same anatomic area as the injury. These contractions may persist for many weeks before gradually subsiding. Localized tetanus may precede the onset of generalized tetanus, but is generally milder.

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(3) Cephalic tetanus is a rare form of the disease, occasionally occurring with otitis media in which clostridium tetani is present in the flora of the middle ear or following injuries to the head. There is involvement of the cranial nerves, especially in the facial area.

(4) Complications of tetanus are common. Laryngospasm or spasm of the muscles of respiration leads to interference with breathing. Fractures of the spine or long bones may result from sustained contractions and convulsions. Hyperactivity of the autonomic nervous system may lead to hypertension or an abnormal heart rhythm. Nosocomial infections are common because of prolonged hospitalization. Secondary infections may include sepsis from indwelling catheters, hospital-acquired pneumonias, and decubitus ulcers. Pulmonary embolism is particularly a problem in persons who use drugs and elderly patients. Aspiration pneumonia is a common late complication of tetanus, found in 50% to 70% of autopsied cases. In recent years, tetanus has been fatal in approximately 11% of reported cases.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. Tetanus cases must be treated in a tertiary care facility with capability to provide long term ICU care and mechanical ventilation. Tetanus immune globulin (TIG) is recommended for persons with tetanus. Intravenous immune globulin (IVIG) contains tetanus antitoxin and may be used if TIG is not available. Because of the extreme potency of the toxin, tetanus disease does not result in tetanus immunity. Active immunization with tetanus toxoid should begin or continue as soon as the person's condition has stabilized.

d. Efficacy of available vaccine(s). Efficacy of the tetanus toxoid has never been studied in a vaccine trial. It can be inferred from protective antitoxin levels that a complete tetanus toxoid series has an efficacy of almost 100%. In the series of 233 cases from 2001–2008, only 7 cases (3%) had received a complete tetanus toxoid series with the last dose within the last 10 years.

e. Periodicity of vaccine boosters. Every 10 years.

f. Likelihood of infection if unvaccinated. While tetanus is rare in the US (averaging 31 cases per year for 2000-2007), nearly all of those cases were in unvaccinated or under-vaccinated individuals. Tetanus is much more common outside the US; in 2015 there were approximately 209,000 infections and about 59,000 deaths globally. As noted above, vaccine efficacy is high, with over 32 times the risk for unvaccinated persons compared to vaccinated.

g. Other methods of prevention. Usual safety measures can help prevent injuries resulting in cuts or puncture wounds from contaminated objects.

h. Efficacy of non-pharmaceutical interventions. At the individual level, such accidents are common and have proven difficult to prevent.

i. Medical opinion on whether other methods of prevention, alone or in concert, will be successful in meeting the compelling government interest. Safety measures alone will not likely be successful in preventing tetanus-prone wounds.

5. Diphtheria

Subj: DISEASES TARGETED WITH MANDATORY VACCINATIONS FOR UNITED STATES NAVY ACTIVE DUTY AND RESERVE PERSONNEL

a. Means of infection. Transmission of diphtheria is most often person-to-person through respiratory droplets. Transmission may also occur from exposure to infected skin lesions or articles soiled with discharges from these lesions. The basic reproduction number is about 2.6.

b. Disease's specific harm to health. This may be a spectrum, but should include worst case scenarios and likelihood of worst case scenarios. Understand that co-morbidities play a significant role in these calculations, and our population tends to lack co-morbidities. The most common form of diphtheria results in a membranous pharyngitis and tonsillitis, with symptoms of fever, sore throat, malaise, and anorexia. While some patients may recover at this point without treatment, others may develop severe disease. The patient may appear quite toxic, but the fever is usually not high. Patients with severe disease may develop marked edema of the submandibular areas and the anterior neck along with lymphadenopathy, giving a characteristic "bull neck" appearance. If enough toxin is absorbed, the patient can develop severe prostration, pallor, rapid pulse, stupor, and coma. Death can occur within 6 to 10 days. Death occurs in 5-10% of diphtheria cases.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. In addition to supportive care, as described for influenza and COVID-19, specific treatments include antitoxin and antibiotics. Diphtheria antitoxin, produced in horses, has been used for treatment of respiratory diphtheria in the United States since the 1890s. Diphtheria antitoxin is available only from CDC, through an Investigational New Drug (IND) protocol. Diphtheria antitoxin does not neutralize toxin that is already fixed to tissues, but it will neutralize circulating toxin and prevent progression of disease.

(1) After a provisional clinical diagnosis of respiratory diphtheria is made, appropriate specimens should be obtained for culture and the patient placed in isolation. Persons with suspected diphtheria should be promptly given diphtheria antitoxin and antibiotics in adequate dosage, without waiting for laboratory confirmation. Respiratory support and airway maintenance should also be provided as needed. Consultation on the use of and access to diphtheria antitoxin is available through the duty officer at CDC's Emergency Operations Center at 770-488-7100.

(2) In addition to diphtheria antitoxin, patients with respiratory diphtheria should also be treated with antibiotics. The disease is usually no longer contagious 48 hours after antibiotics have been given. Elimination of the organism should be documented by two consecutive negative cultures taken 24 hours apart, with the first specimen collected 24 hours after therapy is completed.

d. Efficacy of available vaccine(s). Diphtheria toxoid-containing vaccine has been estimated to have an efficacy of 97%.

e. Periodicity of vaccine boosters. Every 10 years in adults.

Subj: DISEASES TARGETED WITH MANDATORY VACCINATIONS FOR UNITED STATES NAVY ACTIVE DUTY AND RESERVE PERSONNEL

f. Likelihood of infection if unvaccinated. Diphtheria is rare in the U.S. (14 cases were reported between 1996 and 2018), but it is much more common outside the U.S. where vaccination coverage is suboptimal (4,500 cases worldwide in 2015).

g. Other methods of prevention. For diseases transmitted by respiratory droplets such as diphtheria, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination, although widespread vaccination has all but eliminated disease incidence in the U.S. (ex. no cases in 2017 and 2018 according to World Health Organization, which largely eliminated the subsequent need for diphtheria-related NPI in practice). NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

h. Efficacy of non-pharmaceutical interventions. While we are not aware of any studies evaluating the efficacy of NPI specifically for diphtheria, it is likely the effectiveness of most NPI would be similar to that for other infections transmitted by respiratory droplets.

(1) Despite the potential for NPIs to prevent respiratory disease transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing diphtheria outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as diphtheria, especially when only implemented at the individual level and not by the entire community.

6. Pertussis. Note: there is no pertussis vaccine preparation that does not contain tetanus and diphtheria toxoids.

Subj: DISEASES TARGETED WITH MANDATORY VACCINATIONS FOR UNITED STATES NAVY ACTIVE DUTY AND RESERVE PERSONNEL

a. Means of infection. Transmission most commonly occurs person-to-person through contact with respiratory droplets, or by contact with airborne droplets of respiratory secretions. Transmission occurs less frequently by contact with an infected person's freshly contaminated articles. The basic reproduction number is about 5.5.

b. Disease's specific harm to health. The clinical course of pertussis is divided into three stages: catarrhal (with symptoms similar to the common cold lasting 1-2 weeks), paroxysmal (with more severe cough and paroxysms of numerous rapid coughs lasting 1-6 weeks), and convalescent (with gradual recovery over weeks to months). The most common complication and cause of death is secondary bacterial pneumonia, occurring in 13.2% of cases. Between 2000 and 2017, 307 deaths from pertussis were reported to CDC, mostly in children. Adults may also develop complications of pertussis, such as difficulty sleeping, urinary incontinence, pneumonia, rib fracture, syncope, and weight loss

c. Treatment required and level of medical treatment facility capable of delivering that treatment. Varying levels of supportive management are required, depending on severity of disease, as with influenza and COVID-19. Antibiotics are of some value if administered early (i.e., during the first 1 to 2 weeks of cough before coughing paroxysms begin).

d. Efficacy of available vaccine(s). Diphtheria, Tetanus, and Pertussis (DTaP) vaccine efficacy ranged from 80% to 85%, with overlapping confidence intervals.

e. Periodicity of vaccine boosters. Every 10 years.

f. Likelihood of infection if unvaccinated. Reported pertussis incidence has been gradually increasing in the U.S. since the late 1980s and early 1990s, and large epidemic peaks in disease have been observed since the mid-2000s. A total of 48,277 pertussis cases were reported in 2012, the largest number reported since the mid-1950s. Recent outbreaks of pertussis in the U.S. were due to low vaccination rates with large numbers of vaccine refusals (over 75% in one cluster) based on nonmedical reasons. The disease is more common outside the U.S.; an estimated 16.3 million people worldwide were infected in 2015, with 58,700 deaths.

g. Other methods of prevention, such as non-pharmaceutical interventions. For diseases transmitted by respiratory droplets such as pertussis, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

Subj: DISEASES TARGETED WITH MANDATORY VACCINATIONS FOR UNITED STATES NAVY ACTIVE DUTY AND RESERVE PERSONNEL

h. Efficacy of non-pharmaceutical interventions. While we are not aware of any studies evaluating the efficacy of NPI specifically for pertussis, it is likely the effectiveness of most NPI would be similar to that for other infections transmitted by respiratory droplets.

(1) Despite the potential for NPIs to prevent respiratory disease transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing pertussis outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as pertussis, especially when only implemented at the individual level and not by the entire community.

7. My point of contact is (b) (6), MC, USN, Preventive Medicine, who can be reached at (b) (6) or (b) (6)

(b) (6)



COVID-19

Science Brief: COVID-19 Vaccines and Vaccination

Updated Sept. 15, 2021

Summary of Recent Changes

Last updated September 15, 2021



- Data were added indicating that COVID-19 vaccination remains highly effective against COVID-19 hospitalization and death caused by the Delta variant of SARS-CoV-2.
- Data were added from studies published since the last update that further characterize reduced COVID-19 vaccine effectiveness against asymptomatic and mild symptomatic infections with the Delta variant of SARS-CoV-2.
- Data were added from studies published since the last update that suggest decreased vaccine effectiveness against SARS-CoV-2 infection, symptomatic disease, and hospitalization in several groups of immunocompromised persons and potential benefit of a third dose of COVID-19 vaccine in immunocompromised populations.
- Data were added summarizing several small studies of heterologous COVID-19 vaccination series (i.e., mixed schedules), which found that a dose of adenovirus vector vaccine followed by a dose of mRNA vaccine elicits antibody responses at least as high as two doses of mRNA vaccine.
- Data were added from recent studies examining the duration of protection conferred by COVID-19 vaccination.
- Data were added from recent studies describing clinical outcomes and transmissibility of SARS-CoV-2 infections in fully vaccinated persons.

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Key Points

- All COVID-19 vaccines currently approved or authorized in the United States (Pfizer-BioNTech/Comirnaty, Moderna, and Janssen [Johnson & Johnson]) are effective against COVID-19, including against severe disease, hospitalization, and death.
- Available evidence suggests the currently approved or authorized COVID-19 vaccines are highly effective against hospitalization and death for a variety of strains, including Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), and Delta (B.1.617.2); data suggest lower effectiveness against confirmed infection and symptomatic disease caused by the Beta, Gamma, and Delta variants compared with the ancestral strain and Alpha variant. Ongoing monitoring of vaccine effectiveness against variants is needed.
- Limited available data suggest lower vaccine effectiveness against COVID-19 illness and hospitalization among immunocompromised people. In addition, numerous studies have shown reduced immunologic response to COVID-19 vaccination among people with various immunocompromising conditions.
- The risk for SARS-CoV-2 infection in fully vaccinated people cannot be completely eliminated as long as there is continued community transmission of the virus. Early data suggest infections in fully vaccinated persons are more commonly observed with the Delta variant than with other SARS-CoV-2 variants. However, data show fully vaccinated persons are less likely than unvaccinated persons to acquire SARS-CoV-2, and infections with the Delta variant in fully

vaccinated persons are associated with less severe clinical outcomes. Infections with the Delta variant in vaccinated persons potentially have reduced transmissibility than infections in unvaccinated persons, although additional studies are needed.

- This updated science brief synthesizes the scientific evidence supporting CDC's [guidance for fully vaccinated people](#) and will continue to be updated as more information becomes available.

Background

COVID-19 vaccination is a critical prevention measure to help end the COVID-19 pandemic. COVID-19 vaccines are now widely available in the United States, and CDC recommends all people 12 years and older be vaccinated against COVID-19.

On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved an mRNA vaccine (Pfizer-BioNTech/Comirnaty) as a 2-dose series for prevention of symptomatic COVID-19 in persons aged ≥ 16 years. This vaccine is also authorized under an Emergency Use Authorization (EUA) to be administered to prevent COVID-19 in persons aged 12-15 years. A second mRNA vaccine (Moderna), as well as a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector vaccine (Janssen vaccine [Johnson & Johnson]) are authorized under an EUA for use in persons aged ≥ 18 years. Both mRNA vaccines are also authorized for administration of an additional dose to certain immunocompromised persons.

People are considered fully vaccinated if they are ≥ 2 weeks following receipt of the second dose in a 2-dose series (mRNA vaccines), or ≥ 2 weeks following receipt of a single-dose vaccine (Janssen vaccine).*

Public health recommendations for people fully vaccinated with FDA-approved or FDA-authorized COVID-19 vaccines consider evidence of vaccine effectiveness against symptomatic COVID-19 with and without severe outcomes, as well as vaccine impact on SARS-CoV-2 transmission. Other individual and societal factors are also important when evaluating the benefits and potential harms of additional prevention measures (e.g., masking, physical distancing) among vaccinated individuals. The Advisory Committee on Immunization Practices and CDC routinely consider individual health benefits and risks along with factors such as population values, acceptability, and feasibility of implementation when making vaccine recommendations.⁽¹⁾ These factors were also considered when developing CDC's [interim public health recommendations for fully vaccinated people](#).

In this scientific brief, we summarize evidence available through August 24, 2021, for the currently approved or authorized COVID-19 vaccines (administered according to the recommended schedules) and additional considerations used to inform public health recommendations for fully vaccinated people, including:

- Vaccine efficacy and effectiveness against SARS-CoV-2 infection in the general population as well as among immunocompromised persons
- Vaccine effectiveness of heterologous (mixed) vaccination series
- Vaccine performance (i.e., immunogenicity and effectiveness) against emerging SARS-CoV-2 variant viruses, with a particular focus on the [Delta \(B.1.617.2\) variant](#)

Current evidence indicates that fully vaccinated people without immunocompromising conditions are able to engage in most activities with low risk of acquiring or transmitting SARS-CoV-2, with additional prevention measures (e.g. masking) [where transmission is substantial or high](#).

Emerging SARS-CoV-2 viral variants

As of August 28, 2021, the Delta variant of concern (B.1.617.2) is the predominant variant in the United States, with 99% of sequenced specimens being identified as Delta; current data on variant prevalence can be found [on CDC's website](#). The Delta variant, first detected in India, has been shown to have increased transmissibility, potential reduction in neutralization by some monoclonal antibody treatments, and reduction in neutralization by post-vaccination sera.⁽²⁾

Other variants that are either no longer detected or are circulating at very low levels in the United States include: Alpha (B.1.1.7), first detected in the United Kingdom; Beta (B.1.351), first detected in South Africa; Gamma (P.1), first detected in Japan/Brazil; Iota (B.1.526), first detected in the United States-New York; Eta (B.1.525), first detected in the United Kingdom/Nigeria; Kappa (B.1.617.1) and B.1.617.3, first detected in India. These variants have mutations that alter the

receptor binding domain of the spike protein and have variable impact on vaccine effectiveness (notably the E484K/Q mutation in Beta, Gamma, Eta, Iota, Kappa, and B.1.617.3; the N501Y mutation occurring in Alpha, Beta, and Gamma; the E417T/N mutations in Beta and Gamma; and the L452R mutation in Delta, Kappa and B.1.617.3).(2) Vaccine performance against emerging SARS-CoV-2 variants is an important consideration when evaluating the need for prevention measures in vaccinated people and will require continued monitoring.

COVID-19 vaccine efficacy, effectiveness, and immunogenicity

Immunogenicity is the generation of effective protective immunity against a vaccine antigen as measured by laboratory tests. Vaccine efficacy refers to how well a vaccine performs in a carefully controlled clinical trial, and effectiveness describes its performance in real-world observational studies. Evidence demonstrates that the approved or authorized COVID-19 vaccines are both efficacious and effective against symptomatic, laboratory-confirmed COVID-19, including severe forms of the disease. In addition, as shown below, a growing body of evidence suggests that COVID-19 vaccines also reduce asymptomatic infection and transmission. Substantial reductions in SARS-CoV-2 infections (both symptomatic and asymptomatic) will reduce overall levels of disease, and therefore, SARS-CoV-2 virus transmission in the United States. Investigations are ongoing to further assess the risk of transmission from fully vaccinated persons with SARS-CoV-2 infections to other vaccinated and unvaccinated people. Early evidence suggests infections in fully vaccinated persons caused by the Delta variant of SARS-CoV-2 may be transmissible to others; however, SARS-CoV-2 transmission between unvaccinated persons is the [primary cause of continued spread](#).

Animal challenge studies

Rhesus macaque challenge studies provided the first evidence of the potential protective effects of Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines against SARS-CoV-2 infection, including both symptomatic and asymptomatic infection. Vaccinated macaques developed neutralizing antibodies that exceeded those in human convalescent sera and showed no or minimal signs of clinical disease after SARS-CoV-2 challenge.(3-5) In addition, COVID-19 vaccination prevented or limited viral replication in the upper and lower respiratory tracts, which may have implications for transmission of the virus among humans.(3-5)

Vaccine efficacy from human clinical trials

Clinical trials subsequently demonstrated the FDA-approved or authorized COVID-19 vaccines to be efficacious against laboratory-confirmed, symptomatic COVID-19 in adults, including severe forms of the disease, with evidence for protection against both symptomatic and asymptomatic SARS-CoV-2 infection (6-12) (Box). Trial data demonstrated 100% efficacy of the Pfizer-BioNTech vaccine against laboratory-confirmed, symptomatic COVID-19 in adolescents 12–15 years old; this estimate was based on small numbers of cases and prior to emergence of the Delta variant.(13)

Clinical trial data suggest that the Janssen COVID-19 vaccine may have reduced overall efficacy against disease caused by the Beta variant, compared to the other COVID-19 vaccines. Although sero-response rates were similar between U.S. clinical trial participants and those from Brazil and South Africa, vaccine efficacy against moderate to severe-critical COVID-19 after ≥14 days was 74% in the United States (where ~96% of infections were due to the ancestral strain with the D614G mutation), 66% in Brazil (where ~69% of infections were due to Zeta [P.2]), and 52% in South Africa (where ~95% of infections were due to Beta).(14) Notably, Janssen vaccine showed good efficacy against severe or critical disease (73%–82%) across all sites.

Box. Summary of vaccine efficacy estimates for approved or authorized COVID-19 vaccines

All approved or authorized COVID-19 vaccines demonstrated efficacy (range 65% to 95%) against symptomatic, laboratory-confirmed COVID-19 in adults ≥18 years.

- For each approved or authorized COVID-19 vaccine, efficacy was demonstrated across different populations, including elderly and younger adults, in people with and without underlying health conditions, and in people representing different races and ethnicities.
- The Pfizer-BioNTech COVID-19 vaccine also demonstrated high efficacy against symptomatic, laboratory-confirmed COVID-19 in adolescents aged 12-17 years.

All approved or authorized COVID-19 vaccines demonstrated high efficacy (≥89%) against COVID-19 severe enough to require hospitalization.

All approved or authorized COVID-19 vaccines demonstrated high efficacy against COVID-19-associated death.

- In the clinical trials, no participants who received a COVID-19 vaccine died from COVID-19; the Moderna and Janssen vaccine trials among adults ≥ 18 years each had COVID-19 deaths in the unvaccinated placebo arm.


Data from the clinical trials among adults ≥ 18 years old suggest COVID-19 vaccination protects against symptomatic infection and may also protect against asymptomatic infection.

- In the Moderna trial, among people who had received a first dose, the number of asymptomatic people who tested positive for SARS-CoV-2 at their second-dose appointment was approximately 67% lower among vaccines than among placebo recipients (0.1% [n=15] and 0.3% [n=39], respectively)
- Efficacy of Janssen COVID-19 vaccine against asymptomatic infection was 74% in a subset of trial participants.




No trials have compared efficacy between any of the approved or authorized vaccines in the same study population at the same time, making comparisons of efficacy difficult.

- All Phase 3 trials differed by calendar time and geography.
- Vaccines were tested in settings with different background COVID-19 incidence and circulating variants.

Vaccine effectiveness from real-world studies

Multiple studies from the United States and other countries have demonstrated that a two-dose COVID-19 mRNA vaccination series is effective against SARS-CoV-2 infection (including both symptomatic and asymptomatic infections) caused by ancestral and variant strains and sequelae including severe disease, hospitalization, and death. Early evidence for the Janssen vaccine also demonstrates effectiveness against COVID-19 in real-world conditions. There is now a substantial volume of scientific literature examining the effectiveness of COVID-19 vaccination against SARS-CoV-2 infection, symptomatic disease, and other clinical outcomes; detailed summaries of these studies are available in the International Vaccine Access Center's [VIEW-Hub resource library](#) .

Several systematic reviews and meta-analyses of vaccine effectiveness have recently been published (15-17); meta-analyses indicate an average effectiveness of full vaccination against SARS-CoV-2 infection of 85%–95% shortly after completion of vaccination. (16, 17) However, many of the studies in these reviews were conducted prior to the emergence of the variants of concern. Studies in Israel, Europe, and the United Kingdom have demonstrated high real-world effectiveness (>85%) of two doses of Pfizer-BioNTech COVID-19 vaccine while the Alpha variant was prevalent. (18-26) Studies from Qatar have demonstrated high effectiveness against documented infection with Alpha and Beta ≥ 14 days after receiving the Pfizer-BioNTech vaccine (90% and 75%, respectively) and the Moderna vaccine (100% and 96%, respectively); importantly, both vaccines were 96%–100% effective against severe, critical, or fatal disease, regardless of strain. (27, 28) In three studies from Canada, one demonstrated 79% effectiveness for mRNA vaccines against confirmed infection during a time when Alpha and Gamma represented most infections, while another two demonstrated 84% and 88% effectiveness, respectively, against symptomatic infection caused by Gamma/Beta. (29-31)

Individual studies specifically examining vaccine effectiveness against the Delta variant or conducted in the context of substantial circulation of Delta are summarized in Table 1a and as follows. Studies from the United Kingdom have noted effectiveness of the Pfizer-BioNTech vaccine against confirmed infection (79%) and symptomatic infection (88%), compared with the Alpha variant (92% and 93%, respectively). (23, 25) A study from Canada demonstrated 87% effectiveness against symptomatic illness caused by the Delta variant ≥ 7 days after receipt of the second dose of Pfizer-BioNTech vaccine, compared with 89% for the Alpha variant. (32) Data from Qatar demonstrated 54% effectiveness against symptomatic illness for the Pfizer-BioNTech vaccine compared with 85% for the Moderna vaccine. (33). [Preliminary data from South Africa](#)   on the effectiveness of the Janssen vaccine showed 71% effectiveness against hospitalization when Delta variant was predominant, compared to 67% when Beta was predominant. [Data from Israel](#)  also suggest decreased effectiveness of vaccines against infection and illness caused by Delta. The variability in vaccine effectiveness estimates between countries may in part reflect differences in study methodology, intervals used between vaccine doses, and timing of vaccine effectiveness assessments. Of note, the United Kingdom and Canada used prolonged intervals of 12–16 weeks between vaccine doses, which have been observed to induce higher immunogenicity and effectiveness (including in ages ≥ 80 years) (34-37). The most recent estimates from Israel and Qatar represent time points >6 months after initiating respective national vaccination campaigns and 2–5 months after prior assessments of vaccine effectiveness against the Alpha variant, with

potential for waning immunity. Notably, in the United Kingdom, Canada, Qatar, South Africa, and Israel, vaccine effectiveness against hospitalization related to Delta was >90% and comparable to that observed with Alpha for all vaccines currently approved or authorized in the United States.(26, 32, 33)

Table 1a. *Effectiveness of COVID-19 Vaccination Against SARS-CoV-2 Infection and Symptomatic Disease (Including Severe Disease and Hospitalization) Caused by the Delta Variant*

Country	Population	Vaccine	Outcome	Vaccine Effectiveness*
UK ³⁸	General population ≥16 years	Pfizer-BioNTech	Symptomatic disease	88% ¹ (85-90)
Canada ³²	General population ≥16 years	Pfizer-BioNTech	Symptomatic disease	85% ¹ (59-94)
UK (Scotland) ²⁵	General population	Pfizer-BioNTech	SARS-CoV-2 infection	79% ¹ (75-82)
UK ²³	General population	Pfizer-BioNTech	SARS-CoV-2 infection	80% ¹ (77-83)
United States ³⁹	Healthcare workers, first responders, and other essential and frontline workers	Pfizer-BioNTech, Moderna, or Janssen	SARS-CoV-2 infection	66% ¹ (26-84)
United States ⁴⁰	Health system members ≥12 years	Pfizer-BioNTech	SARS-CoV-2 infection	75% ² (71-78)
			Hospitalization	93% ² (84-96)
Qatar ³³	General population ≥12 years	Moderna	SARS-CoV-2 infection	85% ¹ (76-91)
		Pfizer-BioNTech	SARS-CoV-2 infection	54% ¹ (44-61)
		Moderna	Symptomatic disease	86% ¹ (71-94)
		Pfizer-BioNTech	Symptomatic disease	56% ¹ (41-67)
		Moderna	Severe, critical, or fatal disease	100% ¹ (41-100)
		Pfizer-BioNTech	Severe, critical, or fatal disease	90% ¹ (61-98)
UK ²⁶	Patients hospitalized following ED visit	Pfizer-BioNTech	Hospitalization	96% ¹ (86-99)

*Only studies including estimates of vaccine effectiveness ≥7 days following a completed vaccination series of a COVID-19 vaccine currently approved or authorized for use in the United States are included here. For studies that examined variant-specific vaccine effectiveness against multiple variants of SARS-CoV-2, only estimates for effectiveness against the Delta variant are shown. The 95% confidence interval for each estimate of vaccine effectiveness is displayed in parentheses following the estimate.

¹≥14 days after second dose

²≥7 days after second dose

In addition to preventing morbidity and mortality associated with COVID-19, currently approved or authorized vaccines also demonstrate effectiveness against asymptomatic SARS-CoV-2 infection. However, most studies of asymptomatic infection prevention were conducted in the context of circulation of different variants and the effectiveness of COVID-19 vaccines in preventing asymptomatic infection differs by variant and vaccine. In addition, infections identified in such studies as asymptomatic may simply have been identified prior to the infected person developing symptoms, i.e., these infections are presymptomatic rather than asymptomatic. Asymptomatic people are also less likely to be tested for SARS-CoV-2 infection in most settings and thus less likely to be captured in “real world” effectiveness studies.

Table 1b. *Effectiveness of COVID-19 Vaccination Against Asymptomatic SARS-CoV-2 Infection When Different Variants Predominated*

Country	Population	Vaccine	Dominant Variant(s)	Vaccine Effectiveness*
Israel ²⁴	Healthcare workers	Pfizer-BioNTech	Alpha	65% ¹ (45-79)
United States (California) ⁴¹	General population ≥18 years	Pfizer-BioNTech or Moderna	Epsilon, Alpha	68% ² (29-86)
United States ⁴²	Preprocedural adult patients	Pfizer-BioNTech or Moderna	Ancestral strain	80% ³ (56-91)
Qatar ³³	General population ≥12 years	Moderna	Delta	80% ⁴ (54-93)
		Pfizer-BioNTech	Delta	36% ⁴ (11-54)
Israel ⁴³	Healthcare workers	Pfizer-BioNTech	Alpha	86% ⁵ (69-93)
Israel ²¹	General population ≥16 years	Pfizer-BioNTech	Alpha	92% ⁵ (91-92)
Israel ¹⁹	General population ≥16 years	Pfizer-BioNTech	Ancestral strain, Alpha	90% ⁵ (83-94)

*The 95% confidence interval for each estimate of vaccine effectiveness is displayed in parentheses following the estimate.

¹≥11 days after second dose

²≥15 days after second dose

³≥0 days after second dose


⁴≥14 days after second dose

⁵≥7 days after second dose

Vaccine immunogenicity and effectiveness in immunocompromised people

Vaccination is particularly important for people with immunocompromising conditions, who are at increased risk of severe COVID-19 illness. However, current evidence suggests reduced protection from COVID-19 vaccines for many immunocompromised persons. Recent studies in several countries found significantly lower vaccine effectiveness among immunocompromised adults compared to those without immunocompromising conditions (44-46) (Table 2), although each study defined the immunocompromised population differently. Studies in the United States and Israel have also found that immunocompromised persons account for a high proportion (≥40%) of infections among fully vaccinated hospitalized persons. (46, 47)

Compared with those who are not immunocompromised, reduced antibody response to a two-dose primary series of mRNA COVID-19 vaccines has also been observed in specific groups of immunocompromised adults, including people receiving solid organ transplants (48-54): some people with cancer, particularly hematologic cancers (55, 56): some people receiving

hemodialysis for kidney disease (57, 58); and people taking certain immunosuppressive medications (51, 53, 54, 59). While antibody measurement and threshold levels varied by study, a large proportion of immunocompromised persons overall had a measurable immune response after a two-dose series of mRNA vaccine, although some remained seronegative. The distribution of antibody response by immunocompromising condition in [several recent studies](#)  is summarized in Figure 1.

Emerging data suggest an additional COVID-19 vaccine dose in immunocompromised people, typically administered at least 28 days after completion of the primary series, increases antibody response: in small observational studies of solid organ transplant recipients (60-63) or hemodialysis patients (64-66), 33%-54% of persons who had no detectable antibody response to an initial two-dose mRNA vaccine series developed an antibody response to an additional dose of a COVID-19 vaccine. A recently published randomized controlled trial demonstrated substantial increases in serologic immune response to a third dose of Moderna's mRNA vaccine compared with placebo among solid organ transplant recipients who previously received a two-dose series of that vaccine.(67) While these studies evaluated serologic immune response to an additional vaccine dose, the clinical impact of an additional dose on acquisition, severity, and infectiousness of infections in fully vaccinated immunocompromised persons is not yet known.

Table 2. Effectiveness of COVID-19 Primary Series Vaccination Against SARS-CoV-2 Infection and Symptomatic Disease among Immunocompromised Persons

Country	Population	Vaccine	Outcome	Dominant Variant(s)	Vaccine Effectiveness in IC Population	Vaccine Effectiveness in Comparison Population*
United States ⁴⁵	Veterans ≥18 years taking immunosuppressive medications for inflammatory bowel disease	Pfizer-BioNTech or Moderna	SARS-CoV-2 infection	Unknown	69% ¹ (44-83)	No comparison
United States ⁶⁸	Solid organ transplant recipients	Pfizer-BioNTech, Moderna, or Janssen	SARS-CoV-2 infection	Ancestral strain, Alpha	81% ² (50-95)	No comparison
Israel ⁴⁴	General population ≥16 years	Pfizer-BioNTech	SARS-CoV-2 infection	Ancestral strain, Alpha	71% ¹ (37-87)	90%(79-95)
			Symptomatic disease		75% ¹ (44-88)	94%(88-97)
Qatar ⁶⁹	Kidney transplant recipients	Pfizer-BioNTech or Moderna	SARS CoV-2 infection	Alpha, Beta	47% ² (0-74)	No comparison
			Severe, critical, or fatal COVID-19 disease		72% ² (0-91)	
United States ⁴⁶	Hospitalized patients ≥18 years	Pfizer-BioNTech or Moderna	Hospitalization	Ancestral strain, Alpha	59% ² (12-81)	91%(86-95)

IC: Immunocompromised

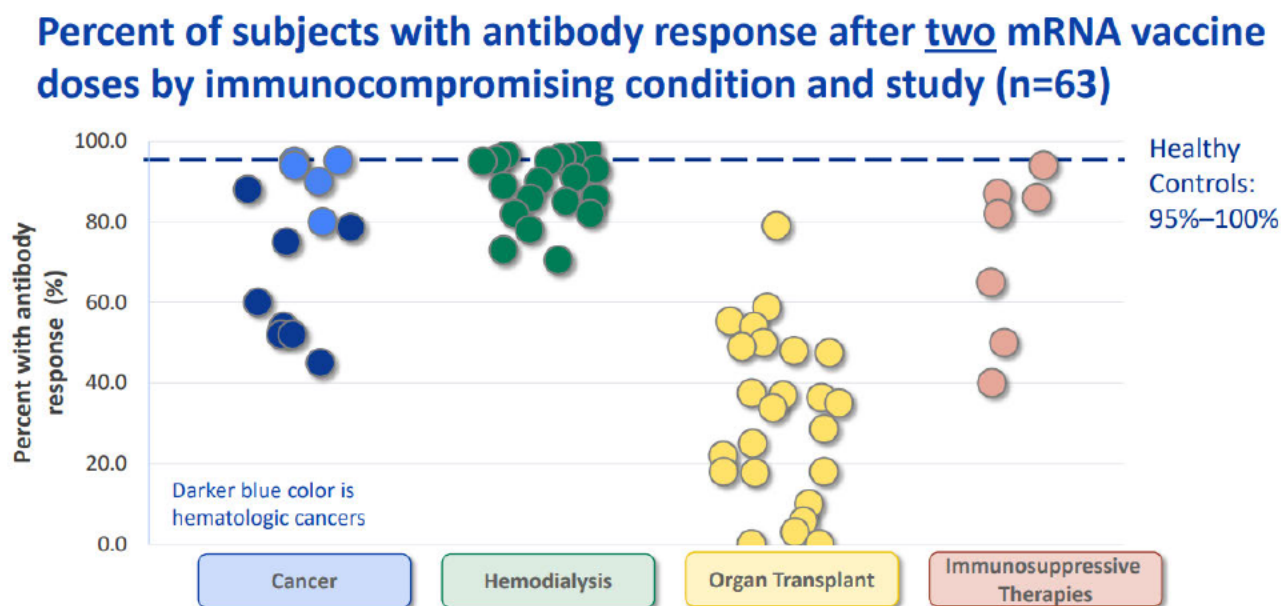
* In the Israeli study, the comparison is with overall vaccine effectiveness (i.e., vaccine effectiveness in the entire study population, including those with immunocompromising conditions). In the U.S. study, the comparison is with vaccine effectiveness among members of the study population without immunocompromising conditions.

The 95% confidence interval for each estimate of vaccine effectiveness is displayed in parentheses following the estimate.

¹ ≥ 7 days after second dose

² ≥ 14 days after second dose

Figure 1:



*The studies displayed in Figure 1 represent the results of a literature review conducted by the Advisory Committee on Immunization Practices' COVID-19 Vaccines Work Group and are current as of July 21, 2021. Numerous additional studies of antibody response to COVID-19 vaccination in various immunocompromised populations have been published since that date and are not captured here.

Vaccine immunogenicity and effectiveness of heterologous (mixed) dosing regimens

Multiple small studies from Europe have examined the immunogenicity of a heterologous or 'mixed' series of COVID-19 vaccines. These studies found that receipt of a dose of AstraZeneca's adenovirus vector vaccine followed by a dose of an mRNA vaccine (most frequently Pfizer-BioNTech) induced a robust immune response (70-72) and was at least as immunogenic as two doses of mRNA vaccines by most measures of immune response.(73-79) One study examined vaccine effectiveness of this heterologous series and estimated an effectiveness of 88% against any SARS-CoV-2 infection two weeks following the mRNA (second) dose.(80) Only one study examined a heterologous series in which the mRNA vaccine was the priming (first) dose; this study found that a dose of Pfizer-BioNTech vaccine followed by a dose of AstraZeneca vaccine did not achieve non-inferiority of immune response when compared with two doses of Pfizer-BioNTech.(81) A single study to date examined heterologous dosing with a primary mRNA vaccine series followed by a dose of the Janssen adenovirus vector COVID-19 vaccine in four subjects and noted substantially increased immune response against SARS-CoV-2 after the third dose.(82)

Vaccine-induced neutralizing antibody activity

Sera from mRNA COVID-19 vaccine (both Pfizer-BioNTech and Moderna) recipients have demonstrated minimal to large reductions in antibody neutralization activity against a variety of mutations, as reviewed in [VIEW-Hub](#) [VIEW-Hub](#). Two related systematic reviews and meta-analyses have also been published (83, 84); however, these reviews do not include all available neutralization studies of the Delta variant with sera from people who received mRNA vaccines or the Janssen vaccine.(85-96) Across studies of VOCs, the greatest reductions were observed for Beta, followed by Gamma and Delta; reductions for Alpha were minimal. The E484K/Q and L452R mutations alone or in combination with other mutations in the receptor binding domain have been shown to account for the majority of the reduction in vaccine-induced neutralizing antibody activity for the Beta, Gamma, and Delta variants.(97-103) Alpha and Iota variants with E484K mutations, which have been detected in the United Kingdom, United States, and other countries, have shown further reductions in neutralization above Alpha and Iota alone, respectively.(87, 97, 104-109) For two-dose COVID-19 vaccines, multiple studies have shown greater neutralization against variants after the second dose (i.e. among fully vaccinated people) compared with after the first dose alone.(88, 91, 97, 98, 110-112)

Robust correlation has been demonstrated between vaccine efficacy and neutralizing antibody levels induced by different vaccines.(119, 120) Based on evidence from clinical trials, the correlate of protection, or antibody threshold providing protection against severe disease, has been estimated to be much lower than that required for protection against confirmed infection.(120) However, in the absence of an accepted antibody threshold that correlates with protection, it is difficult to fully predict how reduced neutralizing activity may affect COVID-19 vaccine effectiveness. Some variants may reduce neutralizing antibody levels to near or below the protective threshold, resulting in lowered vaccine efficacy, increased infections in vaccinated persons, and shortened duration of immunity, and others may not be significant.

Vaccine-induced cellular immunity

Several studies have assessed CD4+ and CD8+ T cell responses from Moderna or Pfizer-BioNTech vaccine recipients to the ancestral SARS-CoV-2 strain compared with the Alpha, Beta, Gamma, and Epsilon variants; these studies observed modest or no defects in cellular immune recognition of the variants.(112, 116, 121-126) Thus, cellular immunity may help limit disease severity in infections caused by variants that partially escape neutralizing antibodies. Variations in the genes encoding human leukocyte antigens have been observed to result in variation of the T cell response to specific SARS-CoV-2 variants, which may impact different subpopulations differently based on genetic prevalence of these variations.(127-132) There are currently no studies of vaccine-induced cellular immunity against the Delta variant.

Older adults and long-term care facility residents

Multiple studies have noted reduced vaccine effectiveness in older adults (≥ 60 years) (38, 133-135) or residents of long-term care facilities, compared with general population estimates.(136-138) Compared with younger individuals, persons aged >80 years have been noted to have reduced T-cell responses, lower neutralizing antibody levels, and less potential antibody diversity (somatic hypermutation), potentially giving this group increased risk for susceptibility to SARS-CoV-2 infection in vaccinated people. (139) Two studies have observed poor antibody response to the Pfizer-BioNTech vaccine among nursing home residents compared with staff (140, 141); one study noted 38% of nursing home residents had undetectable antibodies to the Beta variant at 2–4 weeks after the second dose of Pfizer-BioNTech vaccine, compared with 12% with Moderna vaccine. (140) Another study showed declining antibody levels among nursing home residents, with 72% of residents having undetectable neutralizing antibody levels at 6 months post-vaccination with Pfizer-BioNTech.(142)

Duration of protection

Immunogenicity of COVID-19 vaccines has been demonstrated out to 6–8 months after vaccination.(86, 143) At 2–3 months post vaccination, two studies have shown lower neutralizing titers, including against the Beta and Delta variants, for Janssen (an adenovirus vector vaccine) compared with the mRNA vaccines.(144, 145) Two studies have shown a combined impact of waning antibody levels and reduced neutralization of variants; six months after receiving the Moderna vaccine, neutralizing antibody levels were reduced but sufficient to protect against the ancestral strain, while about 50% of people had undetectable neutralization activity against Beta and Gamma compared with the ancestral strain.(146, 147) However, a small study of people 8 months after receiving the Janssen vaccine had minimal decline in neutralizing titers against Beta, Gamma, and Delta and there was evidence of expanded breadth of neutralizing antibody response against variants over this time period, likely through B cell maturation.(86) More evidence is still needed in this area, including understanding potential differences in the kinetics of immune response related to different vaccine platforms. One recent modeling study based on immunogenicity data predicted that vaccine effectiveness against symptomatic infection caused by the Delta variant may drop below 50% within the first year after vaccination for most current vaccines in use globally, while the majority are protected from severe illness.(148)

Six-month clinical efficacy for the Pfizer-BioNTech vaccine shows an overall efficacy against infection of 91% and 97% efficacy against severe illness.(149) However, a non-significant decrease of six percentage points was observed for every two months ≥ 7 days post-vaccination, from 96% at ≥ 7 days to <2 months, 90% at 2 to <4 months, and 84% at 4 to <6 months. Similar results for the Moderna vaccine have not yet been published, but [data from the manufacturer](#) cite 93% overall efficacy up to 6 months.

Several recent studies have noted decreases over time in the effectiveness of COVID-19 vaccines against SARS-CoV-2 infection. A study of U.S. long-term care residents, who were among the first groups in the United States to be vaccinated, found effectiveness of mRNA vaccination against infection declined from 75% in March–May 2021 to 53% in June–July 2021. (150) A study of adults in one U.S. state found a decline in vaccine effectiveness against SARS-CoV-2 infection from 92% the week of May 3, 2021 to 80% the week of July 19, 2021.(151) Two studies in large U.S. health systems examined mRNA vaccine effectiveness longitudinally from December 2020 and January 2021 through July 2021 and August 2021 and noted marked declines over this period (40, 152): similarly, a large population-based study in the UK identified decreases in effectiveness of

Pfizer-BioNTech vaccination over 4-5 months following the second dose.(153) Observed changes in vaccine effectiveness against infection with SARS-CoV-2 may reflect reduced vaccine performance against the Delta variant, waning immunity from primary vaccination, or other unmeasured confounders. In addition, as people at the highest risk of SARS-CoV-2 infection were generally vaccinated first, observational studies of duration of immunity may be subject to confounding by risk status. Importantly, data as of July 2021 confirm sustained high effectiveness of full mRNA vaccination against COVID-19 hospitalization, even up to 6 months post-vaccination.(151, 154)

A retrospective cohort study in a large healthcare system in Israel noted a 2.3-fold increased risk for infection among fully vaccinated persons who were vaccinated with Pfizer-BioNTech in January vs. April 2021.(155) A similar study observed a higher rate (2.4% v. 1.1%, OR=2.2) of infection in fully vaccinated persons who received the second Pfizer-BioNTech dose ≥ 5 months ago compared with those who received it < 5 months ago, with higher magnitude of difference with increasing age. (156)

Infections in fully vaccinated persons: clinical implications and transmission

As expected, because no vaccine is 100% effective, infections in fully vaccinated persons (e.g. breakthrough [infections](#)) have been observed, albeit at much lower rates than infections among unvaccinated persons; vaccine effectiveness against severe disease remains high. From January through June 2021, COVID-NET data from laboratory-confirmed COVID-19-associated hospitalizations in adults ≥ 18 years of age for whom vaccination status is known showed 3% of hospitalizations occurred in fully vaccinated persons. In general, symptoms and duration of illness in infections among fully vaccinated persons have been attenuated compared with cases among unvaccinated people.(157) CDC conducts nationwide monitoring of [infections in fully vaccinated persons](#) resulting in hospitalization or death. Among hospitalized or fatal cases reported to CDC as of August 30, 2021, 70% of hospitalized cases and 87% of fatal cases of COVID-19 in fully vaccinated persons were in persons aged 65 years or older. Infections in fully vaccinated persons may be associated with lower antibody levels compared with those who maintain protection, as shown in a study of fully vaccinated healthcare workers in Israel with infections caused by the Delta variant.(158) However, infection in a fully vaccinated person may boost immunity; four weeks after an outbreak in a long-term care facility, fully vaccinated residents who experienced SARS-CoV-2 infections were found to have significantly higher antibody levels than vaccinated individuals who did not experience SARS-CoV-2 infections.(159)

The proportions of VOCs observed among cases in fully vaccinated persons has been similar to that observed in [CDC's national genomic surveillance](#).(160) but interpretation of these data are challenging because of local variation and changes in variant proportions over time. An Israeli study of VOC infections in adults fully vaccinated with Pfizer-BioNTech vaccine compared with unvaccinated matched controls, during a time when Alpha was the dominant strain and Beta was detected in $< 1\%$ of all specimens, found a higher proportion of Beta in fully vaccinated cases (matched odds ratio = 8.0) and a higher proportion of Alpha in partially vaccinated cases (matched odds ratio = 2.6), though small sample sizes, especially for Beta, were noted as a limitation.(161) Results of a study from Maryland showed that variants with E484K substitutions (e.g., Beta, Gamma) were associated with increased odds of SARS-CoV-2 infection (OR=2.0) in fully vaccinated persons and infection in fully vaccinated persons associated with hospitalization (OR=2.6), while L452R substitutions (e.g., Delta) were not.(162) However, a study from Houston, Texas observed that Delta caused a significantly higher rate of infections in fully vaccinated people compared with infections from other variants, but noted that only 6.5% of all COVID-19 cases occurred in fully vaccinated individuals(163); similar findings were noted in India.(96)

In studies conducted before the emergence of the Delta variant, data from multiple studies in different countries suggested that people vaccinated with mRNA COVID-19 vaccines who develop COVID-19 generally have a lower viral load than unvaccinated people.(157, 165-169) This observation may indicate reduced transmissibility, as viral load has been identified as a key driver of transmission.(170) Studies from multiple countries found significantly reduced likelihood of transmission to household contacts from people infected with SARS-CoV-2 who were previously vaccinated for COVID-19.(171-176) For the Delta variant, early data indicate vaccinated and unvaccinated persons infected with Delta have similar levels of viral RNA and culturable virus detected, indicating that some vaccinated people infected with the Delta variant of SARS-CoV-2 may be able to transmit the virus to others.(163, 164, 177-180) However, other studies have shown a more rapid decline in viral RNA and culturable virus in fully vaccinated people (96, 177, 180-182). One study observed that Delta infection in fully vaccinated persons was associated with significantly less transmission to contacts than persons who were unvaccinated or partially vaccinated.(181)

Together, these studies suggest that vaccinated people who become infected with Delta have potential to be less infectious than infected unvaccinated people. However, more data are needed to understand how viral shedding and transmission from fully vaccinated persons are affected by SARS-CoV-2 variants, time since vaccination, and other factors, particularly as

transmission dynamics may vary based on the extent of exposure to the infected vaccinated person and the setting in which the exposure occurs. Additional data collection and studies are underway to understand the extent and duration of transmissibility of Delta variant SARS-CoV-2 in the United States and other countries.

Conclusions

COVID-19 vaccines currently approved or authorized in the United States have been shown to provide considerable protection against severe disease and death caused by COVID-19. These findings, along with the early evidence for reduced levels of viral mRNA and culturable virus in vaccinated people who acquire SARS-CoV-2 infection, suggest that any associated transmission risk is substantially reduced in vaccinated people: even for Delta, evidence suggests fully vaccinated people who become infected are infectious for shorter periods of time than unvaccinated people infected with Delta. While vaccine effectiveness against emerging and other SARS-CoV-2 variants will continue to be assessed, available evidence suggests that the COVID-19 vaccines approved or authorized in the United States offer substantial protection against hospitalization and death from emerging variants, including the Delta variant. Data suggest lower vaccine effectiveness against laboratory-confirmed illness and symptomatic disease caused by the Beta, Gamma, and Delta variants compared with the ancestral strain and Alpha variant. Early data also find some decline in vaccine effectiveness against SARS-CoV-2 infection over time, although in fall 2021, 9 months after the start of the U.S. COVID-19 vaccination program, vaccination remains highly protective against hospitalization with COVID-19.

Evidence suggests the U.S. COVID-19 vaccination program has substantially reduced the burden of disease in the United States by preventing serious illness in fully vaccinated people and interrupting chains of transmission. Vaccinated people can still become infected and have the potential to spread the virus to others, although at much lower rates than unvaccinated people. The risks of SARS-CoV-2 infection in fully vaccinated people are higher where community transmission of the virus is widespread. Current efforts to maximize the proportion of the U.S. population that is fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic.

*Note: This brief summarizes evidence related to vaccines approved or authorized for emergency use in the United States. In [specific circumstances](#), CDC guidance for fully vaccinated people can also be applied to COVID-19 vaccines that have been listed for emergency use by the World Health Organization (e.g. AstraZeneca/Oxford) and to some vaccines used for U.S. participants in COVID-19 vaccine trials.

Previous Updates

Updates from Previous Content



As of July 27, 2021

- Data were added from studies published since the last update that demonstrate currently authorized mRNA vaccines provide protection against variants of concern, including the Delta strain that is now predominant in the United States. Vaccine effectiveness against hospitalization and death is high for all current SARS-CoV-2 variants; emerging data suggest lower effectiveness against confirmed infection and symptomatic disease caused by the Beta, Gamma, and Delta variants compared with the ancestral strain and the Alpha variant.




References


Note: Preprints have not been peer-reviewed. They should not be regarded as conclusive, guide clinical practice/health-related behavior, or be reported in news media as established information.









1. Lee G, Carr W, ACIP Evidence Based Recommendations Work Group. Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep. 2018;67(45):1271-2.
2. Centers for Disease Control and Prevention. SARS-CoV-2 Variant Classifications and Definitions [Available from:











3. Corbett KS, Flynn B, Foulds KE, Francica JR, Boyoglu-Barnum S, Werner AP, et al. Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates. *N Engl J Med*. 2020;383(16):1544-55.
4. Mercado NB, Zahn R, Wegmann F, Loos C, Chandrashekar A, Yu J, et al. Single-shot Ad26 vaccine protects against SARS-CoV-2 in rhesus macaques. *Nature*. 2020;586(7830):583-8.
5. Vogel AB, Kanevsky I, Che Y, Swanson KA, Muik A, Vormehr M, et al. BNT162b vaccines protect rhesus macaques from SARS-CoV-2. *Nature*. 2021.
6. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *N Engl J Med*. 2021;384(5):403-16.
7. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine. Vaccines and Related Biological Products Advisory Committee Briefing Document – Sponsor. <https://www.fda.gov/media/144246/download> .
8. Food and Drug Administration. Moderna COVID-19 Vaccine. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document- Sponsor. <https://www.fda.gov/media/144452/download> .
9. Food and Drug Administration. Moderna COVID-19 Vaccine. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document Addendum- Sponsor. <https://www.fda.gov/media/144453/download> .
10. Food and Drug Administration. Janssen COVID-19 Vaccine. Vaccines and Related Biological Products Advisory Committee February 26, 2021 Meeting Briefing Document – Sponsor. <https://www.fda.gov/media/146219/download> .
11. Food and Drug Administration. Janssen COVID-19 Vaccine. Vaccines and Related Biological Products Advisory Committee February 26, 2021 Meeting Briefing Document Addendum – Sponsor. <https://www.fda.gov/media/146218/download> .
12. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *N Engl J Med*. 2020;383(27):2603-15.
13. Food and Drug Administration. Emergency Use Authorization (EUA) Amendment for an Unapproved Product Review Memorandum. <https://www.fda.gov/media/148542/download> .
14. Sadoff J, Gray G, Vandebosch A, Cardenas V, Shukarev G, Grinsztejn B, et al. Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *N Engl J Med*. 2021;384(23):2187-201.
15. Harder T, Koch J, Vygen-Bonnet S, Kulper-Schiek W, Pilic A, Reda S, et al. Efficacy and effectiveness of COVID-19 vaccines against SARS-CoV-2 infection: interim results of a living systematic review, 1 January to 14 May 2021. *Euro Surveill*. 2021;26(28).
16. Kow CS, Hasan SS. Real-world effectiveness of BNT162b2 mRNA vaccine: a meta-analysis of large observational studies. *Inflammopharmacology*. 2021;29(4):1075-90.
17. Shapiro J, Dean NE, Madewell ZJ, Yang Y, Halloran ME, Longini I. Efficacy Estimates for Various COVID-19 Vaccines: What we Know from the Literature and Reports. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.05.20.21257461v2> .
18. Björk J, Inghammar M, Moghaddassi M, et al. Effectiveness of the BNT162b2 vaccine in preventing COVID-19 in the working age population – first results from a cohort study in Southern Sweden. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.04.20.21254636v1> .
19. Dagan N, Barda N, Kepten E, Miron O, Perchik S, Katz MA, et al. BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. *N Engl J Med*. 2021.
20. Goldberg Y, Mandel M, Woodbridge Y, et al. Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1> .
21. Haas EJ, Angulo FJ, McLaughlin JM, Anis E, Singer SR, Khan F, et al. Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalisations, and deaths following a nationwide vaccination campaign in Israel: an observational study using national surveillance data. *Lancet*. 2021.
22. Hall VJ, Foulkes S, Saei A, Andrews N, Oguti B, Charlett A, et al. COVID-19 vaccine coverage in health-care workers in England and effectiveness of BNT162b2 mRNA vaccine against infection (SIREN): a prospective, multicentre, cohort study. *Lancet*. 2021;397(10286):1725-35.
23. Lopez Bernal J, Andrews N, Gower C, Gallagher E, Simmons R, Thelwall S, et al. Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant. *N Engl J Med*. 2021.









24. Regev-Yochay G, Amit S, Bergwerk M, et al. Decreased Infectivity Following BNT162b2 Vaccination: A prospective cohort study in Israel. *The Lancet Regional Health – Europe*. 2021;7(100150).
25. Sheikh A, McMenamin J, Taylor B, Robertson C, Public Health S, the EICC. SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness. *Lancet*. 2021;397(10293):2461-2.
26. Stowe J, Andrews N, Gower C, et al. Effectiveness of COVID-19 vaccines against hospital admission with the Delta (B.1.617.2) variant. *khubnet*. 2021;https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZIEig/view/479607266 .
27. Chemaitelly H, Yassine HM, Benslimane FM, Al Khatib HA, Tang P, Hasan MR, et al. mRNA-1273 COVID-19 vaccine effectiveness against the B.1.1.7 and B.1.351 variants and severe COVID-19 disease in Qatar. *Nat Med*. 2021.
28. Abu-Raddad LJ, Chemaitelly H, Butt AA, National Study Group for C-V. Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants. *N Engl J Med*. 2021.
29. Chung H, He S, Nasreen S, et al. Effectiveness of BNT162b2 and mRNA-1273 COVID-19 vaccines against symptomatic SARS-CoV-2 infection and severe COVID-19 outcomes in Ontario, Canada. *BMJ*. 2021;Aug 20; 374:n1943.
30. Nasreen S, Chung H, He S, et al. Effectiveness of COVID-19 vaccines against variants of concern in Ontario, Canada. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.06.28.21259420v2> .
31. Yassi A, Grant JM, Lockhart K, et al. Infection control, occupational and public health measures including mRNA-based vaccination against SARS-CoV-2 infections to protect healthcare workers from variants of concern: a 14-month observational study using surveillance data. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.05.21.21257600v1> .
32. Nasreen S CH, He S, et al. Effectiveness of COVID-19 vaccines against variants of concern in Ontario, Canada. *medRxiv*. 2021;<https://doi.org/10.1101/2021.06.28.21259420> .
33. Tang P, Hasan MR, Chemaitelly H, et al. BNT162b2 and mRNA-1273 COVID-19 vaccine effectiveness against the Delta (B.1.617.2) variant in Qatar. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.11.21261885v1> .
34. Amirthalingam G, Lopez Bernal J, Andrews NJ, et al. Higher serological responses and increased vaccine effectiveness demonstrate the value of extended vaccine schedules in combatting COVID-19 in England. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.26.21261140v1> .
35. Carazo S, Talbot D, Boulianne N, et al. Single-dose mRNA vaccine effectiveness against SARS-CoV-2 in healthcare workers extending 16 weeks post-vaccination: a test-negative design from Quebec, Canada. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.19.21260445v1> .
36. Flaxman A, Marchevsky N, Jenkin D, et al. Tolerability and Immunogenicity After a Late Second Dose or a Third Dose of ChAdOx1 nCoV-19 (AZD1222). *Preprints with The Lancet*. 2021;https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3873839 .
37. Parry H, Bruton R, Stephens C, Amirthalingam G, Hallis B, Otter A, et al. Extended interval BNT162b2 vaccination enhances peak antibody generation in older people. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.05.15.21257017v1> .
38. Lopez Bernal J, Andrews N, Gower C, Robertson C, Stowe J, Tessier E, et al. Effectiveness of the Pfizer-BioNTech and Oxford-AstraZeneca vaccines on covid-19 related symptoms, hospital admissions, and mortality in older adults in England: test negative case-control study. *BMJ*. 2021;373:n1088.
39. Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021. *MMWR Morb Mortal Wkly Rep*. 2021;ePub: 24 August 2021. DOI: <http://dx.doi.org/10.15585/mmwr.mm7034e4><http://dx.doi.org/10.15585/mmwr.mm7034e4> .
40. Tartof SY, Slezak JM, Fischer H, et al. Six-Month Effectiveness of BNT162B2 mRNA COVID-19 Vaccine in a Large US Integrated Health System: A Retrospective Cohort Study. *Preprints with The Lancet*. 2021;https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3909743 .
41. Andrejko K, Pry J, Myers JF, et al. Early evidence of COVID-19 vaccine effectiveness within the general population of California. *MedRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.04.08.21255135v2> .
42. Tande AJ, Pollock BD, Shah ND, Farrugia G, Virk A, Swift M, et al. Impact of the COVID-19 Vaccine on Asymptomatic Infection Among Patients Undergoing Pre-Procedural COVID-19 Molecular Screening. *Clin Infect Dis*. 2021.
43. Angel Y, Spitzer A, Henig O, et al. Association Between Vaccination With BNT162b2 and Incidence of Symptomatic



















44. Chodick G, Tene L, Rotem RS, Patalon T, Gazit S, Ben-Tov A, et al. The effectiveness of the two-dose BNT162b2 vaccine: analysis of real-world data. Clin Infect Dis. 2021.
45. Khan N, Mahmud N. Effectiveness of SARS-CoV-2 Vaccination in a Veterans Affairs Cohort of Patients With Inflammatory Bowel Disease With Diverse Exposure to Immunosuppressive Medications. Gastroenterology. 2021;161(3):827-36.
46. Tenforde MW, Patel MM, Ginde AA, et al. Effectiveness of SARS-CoV-2 mRNA Vaccines for Preventing Covid-19 Hospitalizations in the United States. medRxiv. 2021;<https://doi.org/10.1101/2021.07.08.21259776> .
47. Brosh-Nissimov T, Orenbuch-Harroch E, Chowers M, Elbaz M, Neshet L, Stein M, et al. BNT162b2 vaccine breakthrough: clinical characteristics of 152 fully vaccinated hospitalized COVID-19 patients in Israel. Clin Microbiol Infect. 2021.
48. Boyarsky BJ, Chiang TP, Ou MT, Werbel WA, Massie AB, Segev DL, et al. Antibody Response to the Janssen COVID-19 Vaccine in Solid Organ Transplant Recipients. Transplantation. 2021;105(8):e82-e3.
49. Boyarsky BJ, Werbel WA, Avery RK, Tobian AAR, Massie AB, Segev DL, et al. Antibody Response to 2-Dose SARS-CoV-2 mRNA Vaccine Series in Solid Organ Transplant Recipients. JAMA. 2021.
50. Chavarot N, Ouedrani A, Olivier M, et al. Poor Anti-SARS-CoV-2 Humoral and T-cell Responses After 2 Injections of mRNA Vaccine in Kidney Transplant Recipients Treated with Belatacept. Transplantation. 2021;105(9):e94-e5.
51. Grupper A, Rabinowich L, Schwartz D, Schwartz IF, Ben-Yehoyada M, Shashar M, et al. Reduced humoral response to mRNA SARS-CoV-2 BNT162b2 vaccine in kidney transplant recipients without prior exposure to the virus. Am J Transplant. 2021.
52. Itzhaki Ben Zadok O, Shaul AA, Ben-Avraham B, Yaari V, Ben Zvi H, Shostak Y, et al. Immunogenicity of the BNT162b2 mRNA vaccine in heart transplant recipients – a prospective cohort study. Eur J Heart Fail. 2021.
53. Rabinowich L, Grupper A, Baruch R, et al. Low immunogenicity to SARS-CoV-2 vaccination among liver transplant recipients. J Hepatol. 2021;75:435-8.
54. Rozen-Zvi B, Yahav D, Agur T, Zingerman B, Ben-Zvi H, Atamna A, et al. Antibody response to mRNA SARS-CoV-2 vaccine among kidney transplant recipients – Prospective cohort study. Clin Microbiol Infect. 2021.
55. Herishanu Y, Avivi I, Aharon A, Shefer G, Levi S, Bronstein Y, et al. Efficacy of the BNT162b2 mRNA COVID-19 Vaccine in Patients with Chronic Lymphocytic Leukemia. Blood. 2021.
56. Monin L, Laing AG, Munoz-Ruiz M, McKenzie DR, Del Molino Del Barrio I, Alaguthurai T, et al. Safety and immunogenicity of one versus two doses of the COVID-19 vaccine BNT162b2 for patients with cancer: interim analysis of a prospective observational study. Lancet Oncol. 2021.
57. Broseta JJ, Rodriguez-Espinosa D, Rodriguez N, Mosquera MDM, Marcos MA, Egri N, et al. Humoral and Cellular Responses to mRNA-1273 and BNT162b2 SARS-CoV-2 Vaccines Administered to Hemodialysis Patients. Am J Kidney Dis. 2021.
58. Simon B, Rubey H, Treipl A, et al. Hemodialysis Patients Show a Highly Diminished Antibody Response after COVID-19 mRNA Vaccination Compared to Healthy Controls. Nephrol Dial Transplant. 2021;1-8.
59. Boyarsky BJ, Ruddy JA, Connolly CM, Ou MT, Werbel WA, Garonzik-Wang JM, et al. Antibody response to a single dose of SARS-CoV-2 mRNA vaccine in patients with rheumatic and musculoskeletal diseases. Ann Rheum Dis. 2021.
60. Charmetant X, Espi M, Benotmane I, et al. Comparison of infected and vaccinated transplant recipients highlights the role of Tfh and neutralizing IgG in COVID-19 protection. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.22.21260852v1> .
61. Kamar N, Abravanel F, Marion O, Couat C, Izopet J, Del Bello A. Three Doses of an mRNA Covid-19 Vaccine in Solid-Organ Transplant Recipients. N Engl J Med. 2021;385(7):661-2.
62. Schrezenmeier E, Rincon-Arevalo H, Stefanski AL, et al. B and T cell responses after a third dose of SARS-CoV-2 vaccine in Kidney Transplant Recipients. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.12.21261966v2.full> .
63. Werbel WA, Boyarsky BJ, Ou MT, Massie AB, Tobian AAR, Garonzik-Wang JM, et al. Safety and Immunogenicity of a Third Dose of SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series. Ann Intern Med. 2021.
64. Ducloux D, Colladant M, Chabannes M, Yannaraki M, Courivaud C. Humoral response after 3 doses of the BNT162b2 mRNA COVID-19 vaccine in patients on hemodialysis. Kidney Int. 2021;100(3):702-4.
65. Espi M, Charmetant X, Barba T, et al. Justification, safety, and efficacy of a third dose of mRNA vaccine in











maintenance hemodialysis patients: a prospective observational study. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.02.21259913v1>  .

66. Longlune N, Nogier MB, Miedouge M, Gabilan C, Cartou C, Seigneure B, et al. High immunogenicity of a messenger RNA based vaccine against SARS-CoV-2 in chronic dialysis patients. *Nephrol Dial Transplant*. 2021.
67. Hall VG, Ferreira VH, Ku T, Ierullo M, Majchrzak-Kita B, Chaparro C, et al. Randomized Trial of a Third Dose of mRNA-1273 Vaccine in Transplant Recipients. *N Engl J Med*. 2021.
68. Aslam S, Adler E, Mekeel K, Little SJ. Clinical effectiveness of COVID-19 vaccination in solid organ transplant recipients. *Transpl Infect Dis*. 2021:e13705.
69. Chemaitelly H, AlMukdad S, Joy JP, et al. SARS-CoV-2 vaccine effectiveness in immunosuppressed kidney transplant recipients. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.07.21261578v1.full>  .
70. Behrens GM, Cossmann A, Stankov MV, Nehlmeier I, Kempf A, Hoffmann M, et al. SARS-CoV-2 delta variant neutralisation after heterologous ChAdOx1-S/BNT162b2 vaccination. *Lancet*. 2021.
71. Borobia AM, Carcas AJ, Perez-Olmeda M, Castano L, Bertran MJ, Garcia-Perez J, et al. Immunogenicity and reactogenicity of BNT162b2 booster in ChAdOx1-S-primed participants (CombiVacS): a multicentre, open-label, randomised, controlled, phase 2 trial. *Lancet*. 2021;398(10295):121-30.
72. Normark J, Vikstrom L, Gwon YD, Persson IL, Edin A, Bjorsell T, et al. Heterologous ChAdOx1 nCoV-19 and mRNA-1273 Vaccination. *N Engl J Med*. 2021.
73. Rose R, Neumann F, Grobe O, et al. Heterologous immunisation with vector vaccine as prime followed by mRNA vaccine as boost leads to humoral immune response against SARS-CoV-2, which is comparable to that according to a homologous mRNA vaccination scheme. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.09.21260251v1>  .
74. Groß R, Zanon M, Seidel A, et al. Heterologous ChAdOx1 nCoV-19 and BNT162b2 prime-boost vaccination elicits potent neutralizing antibody responses and T cell reactivity. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.05.30.21257971v2>  .
75. Schmidt T, Klemis V, Schub D, Mihm J, Hielscher F, Marx S, et al. Immunogenicity and reactogenicity of heterologous ChAdOx1 nCoV-19/mRNA vaccination. *Nat Med*. 2021.
76. Hillus D, Schwarz T, Tober-Lau P, Vanshylla K, Hastor H, Thibeault C, et al. Safety, reactogenicity, and immunogenicity of homologous and heterologous prime-boost immunisation with ChAdOx1 nCoV-19 and BNT162b2: a prospective cohort study. *Lancet Respir Med*. 2021.
77. Tenbusch M, Schumacher S, Vogel E, Priller A, Held J, Steininger P, et al. Heterologous prime-boost vaccination with ChAdOx1 nCoV-19 and BNT162b2. *Lancet Infect Dis*. 2021.
78. Barros-Martins J, Hammerschmidt SI, Cossmann A, Odak I, Stankov MV, Morillas Ramos G, et al. Immune responses against SARS-CoV-2 variants after heterologous and homologous ChAdOx1 nCoV-19/BNT162b2 vaccination. *Nat Med*. 2021.
79. Brehm TT, Thompson M, Ullrich F, et al. Low SARS-CoV-2 infection rate and high vaccine-induced immunity among German healthcare workers at the end of the third wave of the COVID-19 pandemic. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.02.21260667v1>  .
80. Gram MA, Nielsen J, Schelde AB, et al. Vaccine effectiveness when combining the ChAdOx1 vaccine as the first dose with an mRNA COVID-19 vaccine as the second dose. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.26.21261130v1>  .
81. Liu X, Shaw RH, Stuart ASV, Greenland M, Aley PK, Andrews NJ, et al. Safety and immunogenicity of heterologous versus homologous prime-boost schedules with an adenoviral vectored and mRNA COVID-19 vaccine (Com-COV): a single-blind, randomised, non-inferiority trial. *Lancet*. 2021.
82. Iketani S, Liu L, Nair MS, et al. A third COVID-19 vaccine shot markedly boosts neutralizing antibody potency and breadth. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.11.21261670v1>  .
83. Chen X, Chen Z, Azman AS, et al. Comprehensive mapping of neutralizing antibodies against SARS-CoV-2 variants induced by natural infection or vaccination. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.05.03.21256506v1>  .
84. Noori M, Nejadghaderi SA, Arshi S, Carson-Chahhoud K, Ansarin K, Kolahi AA, et al. Potency of BNT162b2 and mRNA-1273 vaccine-induced neutralizing antibodies against severe acute respiratory syndrome-CoV-2 variants of concern: A systematic review of in vitro studies. *Rev Med Virol*. 2021:e2277.
85. Arora P, Kempf A, Nehlmeier I, et al. Increased lung cell entry of B.1.617.2 and evasion of antibodies induced by infection and BNT162b2 vaccination. bioRxiv. 2021;<https://www.biorxiv.org/content/10.1101/2021.06.23.449568v1>  .

86. Barouch DH, Stephenson KE, Sadoff J, et al. Durable Humoral and Cellular Immune Responses Following Ad26.COV2.S Vaccination for COVID-19. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.05.21259918v1>  .
87. Choi A, Koch M, Wu K, et al. Serum Neutralizing Activity of mRNA-1273 against SARS-CoV-2 Variants. bioRxiv. 2021;<https://www.biorxiv.org/content/10.1101/2021.06.28.449914v1>  .
88. Davis C, Logan N, Tyson G, et al. Reduced neutralisation of the Delta (B.1.617.2) SARS-CoV-2 variant of concern following vaccination. MedRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.06.23.21259327v1>  .
89. Edara VV, Pinsky BA, Suthar MS, Lai L, Davis-Gardner ME, Floyd K, et al. Infection and Vaccine-Induced Neutralizing-Antibody Responses to the SARS-CoV-2 B.1.617 Variants. N Engl J Med. 2021.
90. Jongeneelen M, Kaszas K, Veldman D, et al. Ad26.COV2.S elicited neutralizing activity against Delta and other SARS-CoV-2 variants of concern. bioRxiv. 2021;<https://www.biorxiv.org/content/10.1101/2021.07.01.450707v1>  .
91. Liu C, Ginn HM, Dejnirattisai W, Supasa P, Wang B, Tuekprakhon A, et al. Reduced neutralization of SARS-CoV-2 B.1.617 by vaccine and convalescent serum. Cell. 2021.
92. Liu J, Liu Y, Xia H, Zou J, Weaver SC, Swanson KA, et al. BNT162b2-elicited neutralization of B.1.617 and other SARS-CoV-2 variants. Nature. 2021.
93. Lustig Y, Zuckerman N, Nemet I, Atari N, Kliker L, Regev-Yochay G, et al. Neutralising capacity against Delta (B.1.617.2) and other variants of concern following Comirnaty (BNT162b2, BioNTech/Pfizer) vaccination in health care workers, Israel. Euro Surveill. 2021;26(26).
94. Planas D, Veyer D, Baidaliuk A, Staropoli I, Guivel-Benhassine F, Rajah MM, et al. Reduced sensitivity of SARS-CoV-2 variant Delta to antibody neutralization. Nature. 2021;596(7871):276-80.
95. Wall EC, Wu M, Harvey R, Kelly G, Warchal S, Sawyer C, et al. Neutralising antibody activity against SARS-CoV-2 VOCs B.1.617.2 and B.1.351 by BNT162b2 vaccination. Lancet. 2021;397(10292):2331-3.
96. Mlcochova P KS, Dhar MS, et al. . SARS-CoV-2 B.1.617.2 Delta variant emergence and vaccine breakthrough. Research Square. 2021 <https://www.researchsquare.com/article/rs-637724/v1>  .
97. Collier DA, De Marco A, Ferreira I, Meng B, Datir R, Walls AC, et al. Sensitivity of SARS-CoV-2 B.1.1.7 to mRNA vaccine-elicited antibodies. Nature. 2021.
98. Garcia-Beltran WF, Lam EC, St Denis K, Nitido AD, Garcia ZH, Hauser BM, et al. Multiple SARS-CoV-2 variants escape neutralization by vaccine-induced humoral immunity. Cell. 2021.
99. Jangra S, Ye C, Rathnasinghe R, Stadlbauer D, Personalized Virology Initiative study g, Krammer F, et al. SARS-CoV-2 spike E484K mutation reduces antibody neutralisation. Lancet Microbe. 2021.
100. Lucas C, Vogels CBF, Yildirim I, et al. Impact of circulating SARS-CoV-2 variants on mRNA vaccine-induced immunity in uninfected and previously infected individuals. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.14.21260307v1>  .
101. Tada T, Dcosta BM, Samanovic MI, Herati RS, Cornelius A, Zhou H, et al. Convalescent-Phase Sera and Vaccine-Elicited Antibodies Largely Maintain Neutralizing Titer against Global SARS-CoV-2 Variant Spikes. mBio. 2021;12(3):e0069621.
102. Tada T, Zhou H, Dcosta BM, et al. SARS-CoV-2 Lambda Variant Remains Susceptible to Neutralization by mRNA Vaccine-elicited Antibodies and Convalescent Serum. BioRxiv. 2021;<https://www.biorxiv.org/content/10.1101/2021.07.02.450959v1>  .
103. Wang P, Nair MS, Liu L, Iketani S, Luo Y, Guo Y, et al. Antibody Resistance of SARS-CoV-2 Variants B.1.351 and B.1.1.7. Nature. 2021.
104. Annavajhala MK, Mohri H, Zucker JE, Sheng Z, Wang P, Gomez-Simmonds A, et al. A Novel SARS-CoV-2 Variant of Concern, B.1.526, Identified in New York. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.02.23.21252259v4>  .
105. Carreno JM, Alshammary H, Singh G, et al. Reduced neutralizing activity of post-SARS-CoV-2 vaccination serum against variants B.1.617.2, B.1.351, B.1.1.7+E484K and a sub-variant of C.37. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.21.21260961v1>  .
106. Liu Y, Liu J, Xia H, Zhang X, Zou J, Fontes-Garfias CR, et al. BNT162b2-Elicited Neutralization against New SARS-CoV-2 Spike Variants. N Engl J Med. 2021.
107. West AP WJ, Wang JC, et al. Detection and characterization of the SARS-CoV-2 lineage B.1.526 in New York. bioRxiv. 2021;<https://www.biorxiv.org/content/10.1101/2021.02.14.431043v3>  .
108. Wu K, Werner AP, Koch M, Choi A, Narayanan E, Stewart-Jones GBE, et al. Serum Neutralizing Activity Elicited by mRNA-1273 Vaccine. N Engl J Med. 2021.









109. Zhou H, Dcosta B, Samanovic M, et al. B.1.526 SARS-CoV-2 variants identified in New York City are neutralized by vaccine-elicited and therapeutic monoclonal antibodies. *bioRxiv*. 2021;<https://www.biorxiv.org/content/10.1101/2021.03.24.436620v1.full.pdf>  .
110. Alenquer M, Ferreira F, Lousa D, et al. Amino acids 484 and 494 of SARS-CoV-2 spike are hotspots of immune evasion affecting antibody but not ACE2 binding. *bioRxiv*. 2021;<https://www.biorxiv.org/content/10.1101/2021.04.22.441007v2> .
111. Becker M, Dulovic A, Junker D, Ruetalo N, Kaiser PD, Pinilla YT, et al. Immune response to SARS-CoV-2 variants of concern in vaccinated individuals. *Nat Commun*. 2021;12(1):3109.
112. Geers D, Shamier MC, Bogers S, den Hartog G, Gommers L, Nieuwkoop NN, et al. SARS-CoV-2 variants of concern partially escape humoral but not T-cell responses in COVID-19 convalescent donors and vaccinees. *Sci Immunol*. 2021;6(59).
113. Marot S, Malet I, Leducq V, Abdi B, Teyssou E, Soulie C, et al. Neutralization heterogeneity of United Kingdom and South-African SARS-CoV-2 variants in BNT162b2-vaccinated or convalescent COVID-19 healthcare workers. *Clin Infect Dis*. 2021.
114. Planas D, Bruel T, Grzelak L, Guivel-Benhassine F, Staropoli I, Porrot F, et al. Sensitivity of infectious SARS-CoV-2 B.1.1.7 and B.1.351 variants to neutralizing antibodies. *Nat Med*. 2021;27(5):917-24.
115. Shen X, Tang H, McDanal C, Wagh K, Fischer W, Theiler J, et al. SARS-CoV-2 variant B.1.1.7 is susceptible to neutralizing antibodies elicited by ancestral spike vaccines. *Cell Host Microbe*. 2021.
116. Skelly D, Harding A, Gilbert-Jaramillo J, et al. Two doses of SARS-CoV-2 vaccination induce robust immune responses to emerging SARS-CoV-2 variants of concern. *Nature Communications*. 2021;12(5061):1-12.
117. Stamatatos L, Czartoski J, Wan YH, Homad LJ, Rubin V, Glantz H, et al. mRNA vaccination boosts cross-variant neutralizing antibodies elicited by SARS-CoV-2 infection. *Science*. 2021.
118. Supasa P, Zhou D, Dejnirattisai W, Liu C, Mentzer AJ, Ginn HM, et al. Reduced neutralization of SARS-CoV-2 B.1.1.7 variant by convalescent and vaccine sera. *Cell*. 2021.
119. Earle KA, Ambrosino DM, Fiore-Gartland A, Goldblatt D, Gilbert PB, Siber GR, et al. Evidence for antibody as a protective correlate for COVID-19 vaccines. *Vaccine*. 2021;39(32):4423-8.
120. Khoury DS, Cromer D, Reynaldi A, Schlub TE, Wheatley AK, Juno JA, et al. Neutralizing antibody levels are highly predictive of immune protection from symptomatic SARS-CoV-2 infection. *Nat Med*. 2021;27(7):1205-11.
121. Gallagher KME, Leick MB, Larson RC, Berger TR, Katsis K, Yam JY, et al. SARS-CoV-2 T-cell immunity to variants of concern following vaccination. *bioRxiv*. 2021.
122. Lilleri D, Vassaniti I, Bergami F, et al. SARS-CoV-2 mRNA vaccine BNT162b2 elicited a robust humoral and cellular response against SARS-CoV-2 variants. *Research Square*. 2021;<https://www.researchsquare.com/article/rs-396284/v1> .
123. Neidleman J, Luo X, McGregor M, et al. mRNA vaccine-induced SARS-CoV-2-specific T cells recognize B.1.1.7 and B.1.351 variants but differ in longevity and homing properties depending on prior infection status. *bioRxiv*. 2021;<https://www.biorxiv.org/content/10.1101/2021.05.12.443888v2> .
124. Stankov MV, Cossmann A, Bonifacius A, Dopfer-Jablonka A, Ramos GM, Godecke N, et al. Humoral and cellular immune responses against SARS-CoV-2 variants and human coronaviruses after single BNT162b2 vaccination. *Clin Infect Dis*. 2021:1-9.
125. Tarke A, Sidney J, Methot N, et al. Impact of SARS-CoV-2 variants on the total CD4+ and CD8+ T cell reactivity in infected or vaccinated individuals. *Cell Reports Medicine*. 2021;2(7):1-12.
126. Woldemeskel BA, Garliss CC, Blankson JN. SARS-CoV-2 mRNA vaccines induce broad CD4+ T cell responses that recognize SARS-CoV-2 variants and HCoV-NL63. *J Clin Invest*. 2021;131(10).
127. Motozono C, Toyoda M, Zahradnik J, et al. An emerging SARS-CoV-2 mutant evading cellular immunity and increasing viral infectivity. *bioRxiv*. 2021;<https://www.biorxiv.org/content/10.1101/2021.04.02.438288v1> .
128. Pretti MAM, Galvani RG, Farias AS, et al. New SARS-CoV-2 lineages could evade CD8+ T-cells response. *bioRxiv*. 2021;<https://www.biorxiv.org/content/10.1101/2021.03.09.434584v2> .
129. Reynolds CJ, Pade C, Gibbons JM, Butler DK, Otter AD, Menacho K, et al. Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose. *Science*. 2021.
130. Dolton G, Rius C, Hasan MS, et al. Emergence of immune escape at dominant SARS-CoV-2 killer T-cell epitope. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.06.21.21259010v2> .
131. Agerer B, Koblishke M, Gudipati V, Montano-Gutierrez LF, Smyth M, Popa A, et al. SARS-CoV-2 mutations in MHC-I-restricted epitopes evade CD8(+) T cell responses. *Sci Immunol*. 2021;6(57).

132. Buckley PR, Lee CH, Pinho MP, et al. HLA-dependent variation in SARS-CoV-2 CD8+ T cell cross-reactivity with human coronaviruses. *bioRxiv*. 2021;<https://www.biorxiv.org/content/10.1101/2021.07.17.452778v1>  .
133. Aran D. Estimating real-world COVID-19 vaccine effectiveness in Israel using aggregated counts. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.02.05.21251139v3>  .
134. Gomes D, Beyerlein A, Katz K, et al. Is the BioNTech-Pfizer COVID-19 vaccination effective in elderly populations? Results from population data from Bavaria, Germany. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.19.21262266v1>  .
135. Mason T, Whitston M, Hodgson J, et al. Effects of BNT162b2 mRNA vaccine on Covid-19 infection and hospitalisation among older people: matched case control study for England. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.04.19.21255461v1>  .
136. Cavanaugh AM, Fortier S, Lewis P, Arora V, Johnson M, George K, et al. COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program – Kentucky, March 2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(17):639-43.
137. Emborg H, Valentiner-Branth P, Schelde AB, et al. Vaccine effectiveness of the BNT162b2 mRNA COVID-19 vaccine against RT-PCR confirmed SARS-CoV-2 infections, hospitalisations and mortality in prioritised risk groups. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.05.27.21257583v1>  .
138. Moustsen-Helms I, Emborg HD, Nielsen J, et al. Vaccine effectiveness after 1st and 2nd dose of the BNT162b2 mRNA Covid-19 Vaccine in long-term care facility residents and healthcare workers – a Danish cohort study *medRxiv*. 2021;[https://www.medrxiv.org/content/10.1101/2021.03.08.21252200v1\(March](https://www.medrxiv.org/content/10.1101/2021.03.08.21252200v1(March)  24, 2021).
139. Collier DA, Ferreira I, Kotagiri P, Datir RP, Lim EY, Touizer E, et al. Age-related immune response heterogeneity to SARS-CoV-2 vaccine BNT162b2. *Nature*. 2021;596(7872):417-22.
140. Abe KT, Hu Q, Mozafarihashjin M, et al. Neutralizing antibody responses to SARS-CoV-2 variants in vaccinated Ontario long-term care home residents and workers. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.06.21261721v1.full.pdf>   .
141. Pannus P, Neven, K.Y., De Craeye, S., et al. Poor antibody response to BioNTech/Pfizer COVID-19 vaccination in SARS-CoV-2 naïve residents of nursing homes. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.06.08.21258366v1>  .
142. Canaday DH, Oyebanji OA, Keresztesy D, et al. Significant reduction in humoral immunity among healthcare workers and nursing home residents 6 months after COVID-19 BNT162b2 mRNA vaccination. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.15.21262067v1.full.pdf>   .
143. Doria-Rose N, Suthar MS, Makowski M, O'Connell S, McDermott AB, Flach B, et al. Antibody Persistence through 6 Months after the Second Dose of mRNA-1273 Vaccine for Covid-19. *N Engl J Med*. 2021;384(23):2259-61.
144. Tada T, Zhou H, Samanovic M, et al. Comparison of Neutralizing Antibody Titers Elicited by mRNA and Adenoviral Vector Vaccine against SARS-CoV-2 Variants. *bioRxiv*. 2021;<https://doi.org/10.1101/2021.07.19.452771>  .
145. Naranbhai V, Garcia-Beltran, W.F., Berrios Mairena, C., et al. . Immunogenicity of mRNA-1273, BNT162b2 and Ad26.COVS.2 COVID-19 vaccines. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.18.21260732v1>  .
146. Pegu A, O'Connell S, Schmidt SD, O'Dell S, Talana CA, Lai L, et al. Durability of mRNA-1273 vaccine-induced antibodies against SARS-CoV-2 variants. *Science*. 2021.
147. Wu K, Choi A, Koch M, et al. Preliminary Analysis of Safety and Immunogenicity of a SARS-CoV-2 Variant Vaccine Booster. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.05.05.21256716v1>  .
148. Cromer D, Steain M, Reynaldi A, et al. SARS-CoV-2 variants: levels of neutralisation required for protective immunity. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.11.21261876v1>  .
149. Thomas SJ, Moreira ED, Kitchin N, et al. Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1>  .
150. Nanduri S, Pilishvili T, Derado G, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. *MMWR Morb Mortal Wkly Rep*. 2021;ePub: 18 August 2021. DOI: <http://dx.doi.org/10.15585/mmwr.mm7034e3>  .
151. Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. *MMWR Morb Mortal Wkly Rep*. 2021;ePub: 18 August 2021. DOI: <http://dx.doi.org/10.15585/mmwr.mm7034e1>  .
152. Puranik A, Lenahan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. *medRxiv*.

153. Pouwels KB, Pritchard E, Matthews PC, et al. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. 2021;<https://www.ndm.ox.ac.uk/files/coronavirus/covid-19-infection-survey/finalfinalcombinedve20210816.pdf>   .
154. Tendforde MW, Self WH, Naioti EA, et al. Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021. *MMWR Morb Mortal Wkly Rep*. 2021; ePub: 18 August 2021. DOI: <http://dx.doi.org/10.15585/mmwr.mm7034e2>  .
155. Mizrahi B, Lotan R, Kalkstein N, et al. Correlation of SARS-CoV-2 Breakthrough Infections to Time-from-vaccine; Preliminary Study. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.29.21261317v1.full>  .
156. Israel A, Merzon E, Schäffer AA, et al. Elapsed time since BNT162b2 vaccine and risk of SARS-CoV-2 infection in a large cohort. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.03.21261496v1>  .
157. Thompson MG, Burgess JL, Naleway AL, Tyner H, Yoon SK, Meece J, et al. Prevention and Attenuation of Covid-19 with the BNT162b2 and mRNA-1273 Vaccines. *N Engl J Med*. 2021;385(4):320-9.
158. Bergwerk M, Gonen T, Lustig Y, Amit S, Lipsitch M, Cohen C, et al. Covid-19 Breakthrough Infections in Vaccinated Health Care Workers. *N Engl J Med*. 2021.
159. Muller L, Andree M, Ostermann PN, et al. SARS-CoV-2 infection in fully vaccinated individuals of old age strongly boosts the humoral immune response. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.19.21260563v1>  .
160. Centers for Disease Control and Prevention. COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021 [Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm?s_cid=mm7021e3_w.
161. Kustin T, Harel N, Finkel U, Perchik S, Harari S, Tahor M, et al. Evidence for increased breakthrough rates of SARS-CoV-2 variants of concern in BNT162b2-mRNA-vaccinated individuals. *Nat Med*. 2021.
162. Feder KA, Patel A, Vepachedu VR, et al. Association of E484K and L452R spike protein mutations with SARS-CoV-2 infection in vaccinated persons—Maryland, January – May 2021. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.29.21261006v2>  .
163. Musser JM, Christensen PA, Olsen RJ, et al. Delta variants of SARS-CoV-2 cause significantly increased vaccine breakthrough COVID-19 cases in Houston, Texas. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.19.21260808v2>  .
164. Brown CM, Vostok J, Johnson H, Burns M, Gharpure R, Sami S, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings – Barnstable County, Massachusetts, July 2021. *MMWR Morb Mortal Wkly Rep*. 2021;70(31):1059-62.
165. Jones NK, Rivett L, Seaman S, Samworth RJ, Warne B, Workman C, et al. Single-dose BNT162b2 vaccine protects against asymptomatic SARS-CoV-2 infection. *Elife*. 2021;10.
166. Levine-Tiefenbrun M, Yelin I, Katz R, Herzel E, Golan Z, Schreiber L, et al. Initial report of decreased SARS-CoV-2 viral load after inoculation with the BNT162b2 vaccine. *Nat Med*. 2021;27(5):790-2.
167. McEllistrem MC, Clancy CJ, Buehrle DJ, Lucas A, Decker BK. Single dose of a mRNA SARS-CoV-2 vaccine is associated with lower nasopharyngeal viral load among nursing home residents with asymptomatic COVID-19. *Clin Infect Dis*. 2021.
168. Petter E, Mor O, Zuckerman N, et al. Initial real world evidence for lower viral load of individuals who have been vaccinated by BNT162b2. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.02.08.21251329v1>  .
169. Abu-Raddad LJ, Chemaitelly H., Ayoub H.H., et al. Effect of vaccination and of prior infection on infectiousness of vaccine breakthrough infections and reinfections. *medRxiv*. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.28.21261086v1>  .
170. Marks M, Millat-Martinez P, Ouchi D, Roberts CH, Alemany A, Corbacho-Monne M, et al. Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study. *Lancet Infect Dis*. 2021.
171. de Gier B, Andeweg S, Joosten R, Ter Schegget R, Smorenburg N, van de Kasstele J, et al. Vaccine effectiveness against SARS-CoV-2 transmission and infections among household and other close contacts of confirmed cases, the Netherlands, February to May 2021. *Euro Surveill*. 2021;26(31).
172. Harris RJ, Hall JA, Zaidi A, Andrews NJ, Dunbar JK, Dabrera G. Effect of Vaccination on Household Transmission of SARS-CoV-2 in England. *N Engl J Med*. 2021;385(8):759-60.
173. Layan M, Gilboa M, Gonen T. Impact of BNT162b2 vaccination and isolation on SARS-CoV-2 transmission in Israeli households: an observational study. *medRxiv*.

households: an observational study. medRxiv.

2021;<https://www.medrxiv.org/content/10.1101/2021.07.12.21260377v1>  .

174. Prunas O, Warren JL, Crawford FW, et al. Vaccination with BNT162b2 reduces transmission of SARS-CoV-2 to household contacts in Israel. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.13.21260393v1>  .
175. Salo J, Hagg M, Kortelainen M, et al. The indirect effect of mRNA-based Covid-19 vaccination on unvaccinated household members. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.05.27.21257896v2>  .
176. Shah A, Gribben C, Bishop J, et al. Effect of vaccination on transmission of COVID-19: an observational study in healthcare workers and their households. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.03.11.21253275v1>  .
177. Chia PY, Ong SWX, Chiew C, et al. Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.28.21261295v1>  .
178. Griffin JB, Haddix M, Danza P, et al. SARS-CoV-2 Infections and Hospitalizations Among Persons Aged ≥ 16 Years, by Vaccination Status — Los Angeles County, California, May 1–July 25, 2021. MMWR Morb Mortal Wkly Rep. 2021; ePub: 24 August 2021. DOI: <http://dx.doi.org/10.15585/mmwr.mm7034e5>  .
179. Riemersma KK, Grogan BE, Kita-Yarbro A, et al. Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent – Wisconsin, July 2021. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4>  .
180. Shamier MC, Tostmann A, Bogers S. Virological characteristics of SARS-CoV-2 vaccine breakthrough infections in health care workers. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1>  .
181. Kang M, Xin H, Yuan J. Transmission dynamics and epidemiological characteristics of Delta variant infections in China. medRxiv. 2021;<https://www.medrxiv.org/content/10.1101/2021.08.12.21261991v1>  .
182. Ong SWX, Chiew CJ, Ang LW, et al. Clinical and Virological Features of SARS-CoV-2 Variants of Concern: A Retrospective Cohort Study Comparing B.1.1.7 (Alpha), B.1.315 (Beta), and B.1.617.2 (Delta). Preprints with The Lancet. 2021;https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3861566  .

Previous Updates



As of May 27, 2021

- Data were added from studies published since the last update that further demonstrate currently authorized COVID-19 vaccines are effective against SARS-CoV-2 infection, symptomatic and severe disease, and hospitalization with COVID-19.
- Data were added suggesting that currently authorized mRNA vaccines provide protection against variants of concern, including the B.1.1.7 strain that is predominant in the United States.
- Data were added from studies published since the last update that further demonstrate people who are fully vaccinated with a currently authorized mRNA vaccine are protected against asymptomatic infection and, if infected, have a lower viral load than unvaccinated people.

Last Updated Sept. 15, 2021



DoD INSTRUCTION 1300.17

RELIGIOUS LIBERTY IN THE MILITARY SERVICES

Originating Component:	Office of the Under Secretary of Defense for Personnel and Readiness
Effective:	September 1, 2020
Releasability:	Cleared for public release. Available on the Directives Division Website at https://www.esd.whs.mil/DD/ .
Reissues and Cancels:	DoD Instruction 1300.17, "Accommodation of Religious Practices Within the Military Services," February 10, 2009, as amended
Incorporates and Cancels:	Assistant Secretary of Defense for Force Management Policy Memorandum, "Sacramental Use of Peyote by Native American Service Members," April 25, 1997
Approved by:	Matthew P. Donovan, Under Secretary of Defense for Personnel and Readiness

Purpose: In accordance with the authority in DoD Directive 5124.02, this issuance:

- Establishes DoD policy in furtherance of the Free Exercise Clause of the First Amendment to the Constitution of the United States, recognizing that Service members have the right to observe the tenets of their religion, or to observe no religion at all.
- Establishes policy, assigns responsibilities, and provides procedures for the accommodation of religious practices of Service members.
- Establishes DoD policy on the accommodation of individual expressions of sincerely held beliefs (conscience, moral principles, or religious beliefs), which do not have an adverse impact on military readiness, unit cohesion, good order and discipline, or health and safety.
- Establishes DoD policy providing that an expression of sincerely held beliefs (conscience, moral principles, or religious beliefs) may not, in so far as practicable, be used as the basis of any adverse personnel action, discrimination, or denial of promotion, schooling, training, or assignment.
- Implements requirements in Section 2000bb-1 of Title 42, United States Code (U.S.C), also known as "The Religious Freedom Restoration Act" (RFRA), and other laws applicable to the accommodation

of religious practices for DoD to provide, in accordance with the RFRA, that DoD Components will normally accommodate practices of a Service member based on a sincerely held religious belief.

- Requires DoD Components to oversee the development and provision of education and training on the policies and procedures pertaining to the accommodation of religious practices of Service members to commanders, judge advocates, chaplains, recruiters, and other personnel as deemed appropriate by the Military Department or Military Service concerned.

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

a. This issuance applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the “DoD Components”).

b. The definitions, policies, procedures, and assignments of responsibility prescribed in this issuance apply only to the accommodation of religious practices of Service members and in no other context.

1.2. POLICY.

a. Pursuant to the Free Exercise Clause of the First Amendment to the United States Constitution, Service members have the right to observe the tenets of their religion or to observe no religion at all, as provided in this issuance.

b. In accordance with Section 533(a)(1) of Public Law 112-239, as amended, the DoD Components will accommodate individual expressions of sincerely held beliefs (conscience, moral principles, or religious beliefs) which do not have an adverse impact on military readiness, unit cohesion, good order and discipline, or health and safety. A Service member’s expression of such beliefs may not, in so far as practicable, be used as the basis of any adverse personnel action, discrimination, or denial of promotion, schooling, training, or assignment.

c. In accordance with Section 533(b) of Public Law 112-239, as implemented by DoD Instruction 1304.28, no Service member may require a chaplain to perform any rite, ritual, or ceremony that is contrary to the conscience, moral principles, or religious beliefs of the chaplain, nor may any Service member discriminate or take any adverse personnel action on the basis of the refusal by the chaplain to comply with such requirements. This does not preclude disciplinary or administrative action for conduct by a Service member that is proscribed by Chapter 47 of Title 10, U.S.C. (the Uniform Code of Military Justice), including actions and speech that threaten good order and discipline.

d. Requests for religious accommodation will be analyzed under the standard in Paragraph 1.2.e. of this issuance using the process in Section 3 of this issuance. Accommodation of practices reflecting a Service member’s sincerely held conscience or moral principles will be governed by the policies of the DoD Component concerned.

e. DoD Components have a compelling governmental interest in mission accomplishment at the individual, unit, and organizational levels, including such necessary elements of mission accomplishment as military readiness, unit cohesion, good order and discipline, and health and safety. In accordance with RFRA and the guidance in this issuance, DoD Components will normally accommodate practices of a Service member based on sincerely held religious belief.

Accommodation includes excusing a Service member from an otherwise applicable military policy, practice, or duty. In accordance with RFRA, if such a military policy, practice or duty substantially burdens a Service member's exercise of religion, accommodation can only be denied if:

- (1) The military policy, practice, or duty is in furtherance of a compelling governmental interest.
- (2) It is the least restrictive means of furthering that compelling governmental interest.

In applying the standard in Paragraphs 1.2.e.(1) and 1.2.e.(2), the burden of proof is placed upon the DoD Component, not the individual requesting the exemption.

f. Requests for the accommodation of religious practices will be reviewed and acted on as soon as possible, in accordance with this issuance and any DoD Component implementing guidance.

g. In accordance with provisions in Paragraphs 1.2.e and 1.2.f of this issuance, immediate commanders may resolve requests for accommodation of religious practices that do not require a waiver of DoD Component policies regarding the wearing of military uniforms, the wearing of religious apparel, or Service grooming, appearance, or body art standards.

SECTION 2: RESPONSIBILITIES

2.1. ASSISTANT SECRETARY OF DEFENSE FOR MANPOWER AND RESERVE AFFAIRS (ASD(M&RA)).

Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, the ASD(M&RA):

- a. Is responsible for the administration of this issuance and for oversight of the implementation of the policies and procedures it establishes. Issues guidance to the DoD Components, as necessary, concerning the accommodation of religious practices and the implementation of the policies in this issuance.
- b. Acts on Military Department requests regarding limitations on the use, possession, or transportation of peyote cactus for religious practices, in addition to those already listed in Paragraph 3.4. of this issuance, in accordance with Paragraph 3.4.a.(4) of this issuance.

2.2. DOD COMPONENT HEADS OTHER THAN THE SECRETARIES OF THE MILITARY DEPARTMENTS.

The DoD Component heads other than the Secretaries of the Military Departments:

- a. Ensure that requests for the accommodation of religious practices are processed or forwarded for review and action in accordance with this issuance and the implementing regulations and policies of the Military Department and Military Service to which the Service member belongs.
- b. Establish component regulations and policies to address the Service member's sincerely held conscience or moral principles in accordance with Paragraph 1.2.d. of this issuance.

2.3. SECRETARIES OF THE MILITARY DEPARTMENTS.

The Secretaries of the Military Departments:

- a. Adhere to all provisions of this issuance.
- b. Administer their respective programs and update existing regulations and policies, or develop and distribute new guidance, as appropriate, to implement the provisions of this issuance. Implementing issuances will, consistent with this issuance:
 - (1) Establish controls to ensure compliance with established procedures and processing timelines applicable to accommodation requests.
 - (2) Designate appropriate agency officials to review and act on the following:

(a) Requests for the accommodation of religious practices.

(b) Requests for an exemption to an otherwise applicable Military Department or Military Service policy in support of the requesting Service member's exercise of religion or furtherance of religious practices, including, but not limited to, requests pertaining to:

1. Religious apparel, including religious body art.

2. Grooming.

3. Medical practices, including DNA (deoxyribonucleic acid) specimen sampling and immunizations.

(c) Requests from a Service member's command to rescind a previously granted accommodation.

(3) Ensure, to the greatest extent practical, the consistent application of the policies and procedures prescribed by this issuance to similarly situated requests for the accommodation of religious practices throughout their respective Military Departments.

(4) Develop and implement a standards-based approach to the review of, and final action on, requests for the accommodation of religious practices to promote predictable outcomes for the same or similar requests. Such standards will be evidence-based and address commonly requested accommodations. The Military Departments and Military Services will issue or update applicable regulations and policies to authorize officers or officials at the lowest appropriate level of command or supervision to review and take final action on requests for accommodations covered by such standards, in accordance with this issuance. The absence of a standards-based approach to a requested accommodation will not, standing alone, serve as the basis for denying the request. Such a standards-based approach may include:

(a) A list of accommodations of religious practices that may, in ordinary circumstances, be granted to a member serving in a particular military occupational specialty, rating, specialty code, or duty assignment.

(b) Specific guidance on factors to be considered in making individual determinations with regard to a commonly requested or other accommodation of religious practices. Such factors may include those enumerated in Paragraph 3.2.d. of this issuance.

(c). Provide information about the policies and procedures governing the accommodation of religious practices and religious expression to prospective Service members, in accordance with Paragraph 3.2.i. of this issuance.

(d) Request, as appropriate, approval from the ASD(M&RA) regarding limitations on the use, possession, or transportation of peyote cactus for religious practices, in addition to those already listed in Paragraph 3.4. of this issuance, in accordance with Paragraph 3.4.a.(4) of this issuance.

(5) Oversee the development and provision of education and training on the policies and procedures pertaining to the accommodation of religious practices of Service members to:

- (a) Commanders.
- (b) Judge advocates.
- (c) Chaplains.
- (d) Recruiters.
- (e) Other personnel as deemed appropriate by the Military Department or Military Service concerned.

SECTION 3: PROCESSING ACCOMMODATION REQUESTS

3.1. ACCOMMODATION REQUESTS.

a. Service members submitting a request for accommodation will continue to comply with the policy, practice, or duty from which an accommodation has been requested unless and until informed that the request has been approved by the appropriate authority. Exceptions to this requirement may only be granted in exceptional circumstances, in accordance with the implementing regulations and policies promulgated by the Military Department and Military Service concerned.

b. Requests for accommodation submitted by a cadet or midshipman enrolled at a Military Service Academy or in a Senior Reserve Officers' Training Corps program will be addressed in accordance with this issuance and the implementing regulations and policies promulgated by the Military Department and Military Service concerned.

c. Nothing in this issuance precludes disciplinary or administrative action for conduct by a Service member that is prohibited by Chapter 47 of Title 10, U.S.C., also known as "The Uniform Code of Military Justice."

3.2. REVIEW OF AND ACTION ON REQUESTS FOR THE ACCOMMODATION OF RELIGIOUS PRACTICES.

a. Adjudication Authority.

Requests for the accommodation of religious practices that can be approved consistent with Military Department and Military Service regulations or policies, (e.g., current uniform and grooming standards) will be reviewed and acted on at the lowest appropriate level of command or supervision, as provided in the regulations and policies of the Military Department and Military Service concerned and in accordance with this issuance. Requests for the accommodation of religious practices that require the waiver of otherwise applicable Military Department and Military Service regulations and policies will be forwarded to the Secretary of the Military Department concerned. Records concerning requests for accommodations will be maintained in accordance with DoD Instruction 5400.11.

b. Delegation.

The Secretary of a Military Department may delegate, in writing, the authority to act on requests for the accommodation of religious practices that require the waiver of otherwise applicable Military Department and Military Service regulations and policies only as described in Paragraph 3.2.b.(1) through 3.2.b.(3).

(1) Department of the Army.

Delegation may be no lower than the Deputy Chief of Staff, G-1.

(2) Department of the Navy.

Delegation may be no lower than the Chief of Naval Personnel, or the Deputy Commandant of the Marine Corps for Manpower and Reserve Affairs, as appropriate.

(3) Department of the Air Force.

Delegation may be no lower than the Air Force Deputy Chief of Staff for Manpower, Personnel, and Services, or the Deputy Chief of Space Operations for Personnel and Logistics Services, as appropriate.

c. Review and Action Timelines.

Requests for the accommodation of religious practices will be reviewed and acted on as soon as practicable, and no later than the timelines provided in Table 1. Exceptions to this review and action timeline may be granted only in exceptional circumstances, as determined by the regulations and policies of the Military Department and Military Service concerned.

Table 1. Review and Action Timeline for Processing Accommodation Requests

Action to be Taken	For Requests Within the United States	For Requests Outside the United States or for Reserve Component Service Members Not on Active Duty
Action on Requests for Religious Accommodation that Can Be Approved Consistent with Existing Military Department or Military Service Regulations or Policies		
Review and final action completed and written notification to requesting Service member provided	No later than 30 business days from Service member submission	No later than 60 days from Service member submission
Action on Requests for Religious Accommodation that Require the Waiver of Otherwise Applicable Military Department or Military Service Regulations or Policies		
Written request for accommodation received by the Office of the Secretary concerned ¹	No later than 30 days from Service member submission to commander or supervisor	No later than 60 days from Service member submission to commander or supervisor
Review and final action completed and written notification to requesting Service member provided	No later than 60 days from receipt by the Office of the Secretary concerned. ¹ Must be provided to the Service member within 5 days of final action	
¹ Unless authority is delegated to a subordinate official in accordance with Paragraph 3 2 b of this issuance		

d. Factors for Consideration.

Officials charged with making recommendations or taking final action on a Service member's request for the accommodation of religious practices will review each request

individually, considering the full range of facts and circumstances relevant to the specific request. Factors to consider include:

(1) The compelling governmental interest in mission accomplishment, including military readiness, unit cohesion, good order and discipline, or health and safety.

(2) Alternate means available to address the requested accommodation. The means that is least restrictive to the requestor's religious practice and that does not impede a compelling governmental interest will be determinative.

e. Notice of Resolution.

A Service member will be promptly informed of the approval or disapproval of his or her request for accommodation in accordance with Table 1.

(1) A Service member's request for the accommodation of religious practices may be granted in whole or in part. The Service member will be informed in writing of any conditions or limitations placed on the grant that are necessary to meet the DoD's compelling governmental interest in mission accomplishment, such as, for example, conditions related to:

(a) Deployment;

(b) Health and safety issues relative to particular assignments or types of assignments; or

(c) Training events or ceremonial occasions that require a Service member to conform to military standards to protect health and safety, or maintain good order and discipline.

(2) A Service member whose request is granted in part will be informed, in writing, of the specific elements of that approval.

f. Administrative Appeal Process.

The regulations and policies of a Military Department or Military Service implementing this issuance will provide a process for Service members to appeal the denial of a request for accommodation of religious practices, or any condition on such accommodation. Appeals will be sent to an official in the chain of command or chain of supervision above the officer or official who took final action on the request. No further administrative appeal will be available for a decision made by the Secretary of the Military Department.

g. Accommodation Duration and Proposals to Rescind a Granted Accommodation.

An approved request for accommodation will remain in effect during follow-on duties, assignments, or locations, and for the duration of a Service member's military career, including after promotions, reenlistment or commissioning, unless and until rescinded in accordance with the requirements of this issuance.

(1) In accordance with this issuance and the implementing policies and regulations of the Military Department and Military Service concerned, an approved accommodation may be subject to review and rescission, in whole or in part, at any time, based upon a determination that the circumstances under which the grant of accommodation was approved have changed (e.g., deployment, new duties, or other material change in circumstances). The Military Department or Military Service concerned—not the individual Service member—bears the burden of initiating a proposal to review and rescind an accommodation previously granted.

(2) When a Military Department or Military Service initiates a proposal to review and rescind an accommodation previously granted, an appropriate officer or official will forward a written summary of the nature of the materially changed circumstances that require such review and repeal to the Service member concerned for comment.

(a) The Service member will be:

1. Allotted no fewer than 10 days to review and comment on the proposed rescission of the accommodation.

2. Afforded the opportunity to review and comment on any endorsements of this proposal from the chain of command.

3. Afforded, subject to security classification requirements, the opportunity to review and comment on any documents or attachments to the proposal or subsequent endorsements.

(b) Any comments submitted by the Service member will be forwarded for consideration by the appropriate official authorized to act on the matter, in accordance with this issuance.

(3) A proposal to review and rescind a previously approved accommodation must be acted on at a level of authority no lower than that at which the accommodation was granted, in accordance with this issuance and the regulations and policies of the Military Department and Military Service concerned implementing this issuance. The standard for repealing a previously granted accommodation, in whole or in part, is the same as the standard for denying a request for the accommodation of religious practices in the first place, and the same factors must be considered, as appropriate.

h. Accommodation Modification or Suspense Under Exigent Circumstances.

Under exigent circumstances and in furtherance of a compelling governmental interest due to operational necessity, when time is of the essence and no less restrictive means of religious accommodation are available, a commander at a level determined by the Military Department or Military Service concerned may temporarily modify or suspend accommodations granted, upon notice to the Service member concerned and without benefit of appeal. The level of this commander must be no lower than the officer exercising Summary Court-Martial Convening Authority over a Service member who has previously been granted an accommodation of religious practices.

(1) To the extent practicable, the commander concerned, if not a general officer or flag officer, or member of the senior executive service, will notify, in advance, the first general officer or flag officer, or member of the senior executive service, as appropriate, in the affected Service member's chain of command or supervision, of the commander's intent to modify or suspend a previously granted accommodation. When such advance notice is not practicable, the commander concerned will notify the appropriate general officer or flag officer, or member of the senior executive service, as appropriate, as soon as circumstances permit.

(2) The Service member concerned may be required to immediately comply with the modification or suspension of an accommodation, if circumstances so warrant.

(3) The modification or suspension of the accommodation will apply for only the minimum period required by the circumstances.

i. Pre-accession Procedures.

(1) Applicants to the Military Services will be informed of the policies and procedures for the accommodation of religious practices in accordance with this issuance, and as implemented by the Military Department or Military Service concerned. These applicants include individuals who apply for:

- (a) A commissioning program;
- (b) A warrant officer program;
- (c) Enlistment or entry in the Military Services;
- (d) Reenlistment (or reentry) in the Military Services;
- (e) Enrollment in a Military Service Academy or a Senior Reserve Officers' Training Corps program (including Military Service Academy preparatory schools); or
- (f) The award of a scholarship or other benefit that requires a commitment to serve as a Service member.

(2) The Military Departments and Military Services will develop processes for the review and action on pre-accession requests for the accommodation of religious practices and establish those processes in appropriate regulations and policies. Such processes must provide applicants the opportunity to submit a request for accommodation of religious practices, and receive a final decision on that request, before participation in the commissioning program, warrant officer program, enlistment, reenlistment, enrollment in a Military Service Academy or a Senior Reserve Officers' Training Corps program, or award of such scholarship or benefit. The review and processing of such requests must be consistent with this issuance.

3.3. REQUIRED PRINCIPLES AND RULES FOR MILITARY REGULATIONS AND POLICIES.

DoD Component regulations and policies must include the following principles and rules:

a. Worship practices, holy days, and Sabbath or similar religious observance requests will be accommodated to the extent possible, consistent with mission accomplishment and will normally not require a religious accommodation request.

b. A Service member's religious practices will be considered in acting on a request for separate rations. Accommodation requests for separate rations may be adjudicated at the command level.

c. A Service member's religious practices will be considered in acting on a request for exemption from required medical practices. Action on a request for medical exemption must be consistent with mission accomplishment, including consideration of potential medical risks to other persons comprising the unit or organization.

d. The following rules govern the wear of items of religious apparel:

(1) In accordance with Section 774 of Title 10, U.S.C., Service members may wear items of religious apparel while in uniform, except in circumstances in which wearing the item would interfere with the performance of the member's military duties or the item of apparel is not neat and conservative. The Military Departments and Military Services will prescribe regulations governing the wear of such items. Factors that may be considered in determining whether an item of religious apparel interferes with military duties include, but are not limited to, whether the item:

(a) Impairs the safe and effective operation of weapons, military equipment, or machinery.

(b) Poses a health or safety hazard to the Service member wearing the religious apparel or to others.

(c) Interferes with the wear or proper function of special or protective clothing or equipment (e.g., helmets, protective masks, wet suits).

(d) Otherwise impairs mission accomplishment.

(2) Religious items or articles not visible or apparent may be worn with the uniform, provided they do not interfere with the performance of the Service member's military duties, as described in Paragraph 3.3.d.(1) of this issuance, and do not interfere with the proper wear of any authorized article of the uniform.

(3) Under regulations and policies of the Military Department and Military Service concerned, religious headgear may be worn with the uniform whenever a military cap, hat, or other headgear is not prescribed. Religious headgear may also be worn underneath prescribed

military headgear, provided it does not interfere with the proper wear, function, or appearance of the headgear, as described in Paragraph 3.2.d.(1).

(4) Notwithstanding any other provision in this issuance, while conducting worship services and during the performance of rites and rituals associated with his or her religious faith, a chaplain may wear with the military uniform any required religious apparel or accouterments associated with the traditions or practices of his or her religious faith.

(5) In evaluating requests for the accommodation of religious practices related to body art, these factors will be among those considered:

(a) Whether the body art is neat and conservative.

(b) The location of the body art, including whether the body art is visible when the Service member is wearing the military uniform.

3.4. ADDITIONAL GUIDANCE REGARDING THE USE OF PEYOTE.

a. There are additional rules governing the use of peyote in religious practices. In accordance with Section 1996a of Title 42, U.S.C. (also known as the “American Indian Religious Freedom Act Amendments of 1994”), Service members who are members of Indian tribes as defined in that statute may use, possess, or transport the peyote cactus as a religious sacrament in connection with the bona fide practice of a traditional Indian religion, and will not be penalized or discriminated against on the basis of such use, possession, or transportation. Reasonable limitations on the use, possession, transportation, or distribution of peyote may be imposed to promote military readiness, promote safety, or comply with international law or laws of other countries. The Secretaries of the Military Departments will prescribe regulations authorizing the use, possession, or transportation of peyote cactus and imposing limitations on such use, possession, or transportation including, but not limited to, the following:

(1) Peyote will not be used on duty or within 24 hours before scheduled military duty.

(2) Peyote may be possessed in amulet form, not for ingestion, and such an amulet may be worn as an item of religious apparel subject to Military Service uniform regulations. Otherwise, peyote will not be used, possessed, distributed, or introduced aboard military vehicles, vessels, or aircraft or, except when permitted by the installation commander, on military installations.

(3) A Service member who has used peyote will promptly notify their commander upon return to duty after such use.

(a) The Secretary of the Military Department concerned may require pre-use notification by Service members performing designated duties when it is in the interest of military readiness or safety to notify commanders of a Service member’s intent to use peyote.

(b) Upon notification of use or intended use of peyote, the Service member will provide documentation verifying membership in an Indian tribe as defined by Section 1996a(c)(2) of Title 42, U.S.C.

(4) The establishment by the Secretary of a Military Department of limitations on the use, possession, or transportation of peyote cactus, in addition to those already listed in Paragraph 3.4. of this issuance, must be consistent with RFRA, the Free Exercise Clause of the First Amendment to the Constitution of the United States, any other applicable statutes such as the American Indian Religious Freedom Act Amendments of 1994, and this issuance. Any such additional limitations must be approved, in advance, by the ASD(M&RA). Before approving any additional limitation proposed by the Secretary of a Military Department, the ASD(M&RA) will consult with representatives of traditional Indian religions for which the sacramental use of peyote is integral to their practice, pursuant to Section 1996a(b)(7) of Title 42, U.S.C.

b. Requests by Service members for the accommodation of a religious practice involving the use, possession, or transportation of any substance other than peyote, the use, possession, transportation, manufacturing, or distribution of which is prohibited by law or policy, will be forwarded to the Secretary of the Military Department concerned for resolution. Before taking final action on any such accommodation request, the Secretary of the Military Department concerned will notify the ASD(M&RA).

GLOSSARY

G.1. ACRONYMS.

ACRONYM	MEANING
ASD(M&RA)	Assistant Secretary of Defense for Manpower and Reserve Affairs
RFRA	Religious Freedom Restoration Act
U.S.C.	United States Code

G.2. DEFINITIONS.

These terms and their definitions are for the purpose of this issuance.

TERM	DEFINITION
compelling government interest	In the DoD, a military requirement that is essential to accomplishment of the military mission. In accordance with Paragraph 1.2.e. of this issuance, DoD Components have a compelling governmental interest in mission accomplishment at the individual, unit, and organizational levels, including such necessary elements of mission accomplishment as military readiness, unit cohesion, good order and discipline, and health and safety.
neat and conservative	<p>In the context of the wear of a military uniform, items of religious apparel that:</p> <p>Are discreet, tidy, and not dissonant or showy in style, size, design, brightness, or color.</p> <p>Do not replace or interfere with the proper wear of any authorized article of the uniform.</p> <p>Are not temporarily or permanently affixed or appended to any authorized article of the uniform.</p>
pre-accession	The period of time before a prospective Service member's participation in a commissioning program, warrant officer program, enlistment (or entry), reenlistment (or reentry), or enrollment in a Military Service Academy or a Senior Reserve Officers' Training Corps program.

TERM	DEFINITION
religious apparel	Articles of clothing, jewelry or other such accoutrements the wearing of which is part of the observance of the religious faith practiced by the Service member.
religious body art	Temporary or permanent tattoos, piercings through the skin or body parts, or other modifications to the body that are a part of a Service member's religious practice.
religious practice	An action, behavior, or course of conduct constituting individual expressions of religious beliefs, whether or not compelled by, or central to, the religion concerned.
substantial burden	<p>A governmental act is a substantial burden to a Service member's exercise of religion if it:</p> <ul style="list-style-type: none">Requires participation in an activity prohibited by a sincerely held religious belief;Prevents participation in conduct motivated by a sincerely held religious belief; orPlaces substantial pressure on a Service member to engage in conduct contrary to a sincerely held religious belief.

REFERENCES

DoD Directive 5124.02, “Under Secretary of Defense for Personnel and Readiness (USD(P&R)),” June 23, 2008

DoD Instruction 1304.28, “Guidance for the Appointment of Chaplains for the Military Departments,” June 11, 2004, as amended

DoD Instruction 5400.11, “DoD Privacy and Civil Liberties Programs,” January 29, 2019

Section 533 of Public Law 112-239, the “National Defense Authorization Act for Fiscal Year 2013,” December 18, 2012, as amended

United States Code, Title 10

United States Code, Title 42

United States Constitution